NICE Maternal and Child Nutrition programme

Review 3: The effectiveness of public health interventions to improve the nutrition of postpartum women

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A review prepared for NICE by:

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1. Executive Summary

This rapid review examines the effectiveness of public health interventions for postpartum mothers that aimed to improve maternal nutrition and health. In particular, this rapid review sought to assess studies that targeted mothers in low-income households.

The search strategy was conducted in February 2006 using a stepped approach. Initially, a worldwide search was conducted to identify potentially relevant systematic reviews (from 1995 onwards) followed by randomised controlled trials (1990 onwards) and other study types (conducted in the UK and published from 1990 onwards). A total of 5784 citations were independently screened by two reviewers, and full paper copies of 16 systematic reviews, 72 randomised controlled trials and four UK studies were also independently screened by two reviewers. Fourteen randomised controlled trials (reported in 18 papers) were data extracted and quality assessed by one reviewer and checked by a second reviewer. No relevant systematic reviews or UK studies were identified. In addition, no studies that evaluated the promotion of effective interventions, including micronutrient supplementation (e.g. folic acid) were found in the literature search.

Four studies (reported in five papers) provide a body of 1- evidence suggesting that diet and exercise interventions can be effective in enabling some postpartum women to lose weight gained during pregnancy. The four studies (O’Toole 2003, Lovelady 2000, McCrory 1999, Leermakers 1998) all took place in the US among predominantly white women who were not noted to be from disadvantaged groups. Participants included in the analyses appeared highly motivated to lose weight. These studies would appear to be directly applicable to similar women in the UK.

One study (Lagstrom 1999) with 1- evidence suggests that individualised, regularly updated, face-to-face advice for parents about specific fats in their child’s diet may have a secondary effect on maternal intake of fats and maternal cholesterol levels at five years postpartum, but no effect on BMI. Broader applicability of this evidence is uncertain.

A further nine studies were identified (reported in thirteen papers) which investigated the effects of various supplements on maternal nutritional status in the postpartum period.

There is a dearth of good quality evidence in relation to many of the questions that matter to postpartum women, especially those from low-income groups. Studies of nutritionally vulnerable women are scarce. In spite of the scale of the problem, and the potential for real benefit both for women and for their families, effective ways of addressing the practical and emotional problems that restrict women’s nutritional intake following the birth of a baby remain unclear.

1.1. Diet and physical activity programmes

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<td>O’Toole ML, Sawicki MA, et al. Structured diet and physical activity prevent postpartum weight retention. <em>Journal of Women's Health</em> 2003;12,10:991-8.</td>
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### 1.2. Dietary counselling

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### 1.3. Micronutrient supplementation

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2. Evidence statements

1. There is evidence from four RCT’s (Leermakers et al 1998; Lovelady et al 2000 and 2006; McCrory et al 1999; and O’Toole et al 2003 all 1-) that diet and exercise programmes are effective in enabling some post partum women to lose weight gained during pregnancy. This finding is based on US studies of women not noted to be from disadvantaged groups and who appear to be highly motivated to lose weight.

2. There is evidence from 2 RCT’s (Lovelady et al 2000 , 2006; McCrory et al 1999 both 1-) that a combination of diet and physical activity results in more effective and preferable weight loss than diet alone or physical activity alone.

3. There is evidence from an RCT (McCrory et al 1999, 1-) that physical activity as part of a combined diet and physical activity intervention to promote weight loss, is more effective when frequent and regular, than when vigorous and less frequent.

4. There is evidence from 2 RCT’s (Leermakers et al 1998; O’Toole et al 2003 both 1-) that integrated programmes of activity which support participants in combining diet and regular physical activity in order to promote weight loss in the post partum period are more effective than interventions which provide information alone.

5. There is evidence from 2 RCT’s (Leermakers et al 1998; O’Toole et al 2003 both 1-) that the characteristics of programmes which are effective in enabling some women to lose weight in the post partum period are those which: combine diet and physical activity; include strategies for behaviour change; tailor the intervention to individual or group needs; include some group sessions and written materials; provide ongoing support and contact with programme staff; and are of a sufficient duration to make sustained lifestyle changes.

6. There is evidence from one RCT (McCrory et al 1999 1-) that short term weight loss of 1kg /week achieved through a combination of diet plus physical activity in healthy post partum women has no detrimental effect on milk quantity or quality and does not appear to affect infant weight gain.

A second RCT (Lovelady et al 2000, 2006,1-) combining diet and physical activity in healthy post partum women (BMI 25-30) over a longer time period and resulting in a mean weight loss of 0.5kg/week did not appear to affect infant weight or length. However the study may not have been sufficiently powered to demonstrate such effects.

7. There is evidence from two RCT’s (Jensen et al 2000; Helland et al 1998 both 1-) that supplementing mothers up to the eighth week post partum with supplements of docasahexanoic acid (DHA) from a variety of sources increases the amount of DHA in maternal plasma and in breast milk in a dose dependent manner.

8. There is evidence from two RCT’s (Mara et al 2001, 1-, and Krafft et al 2005 1++) that supplementing women with iron from early in the post partum period for at least two months can significantly increase levels of haemoglobin compared to non-supplemented controls.
9. There is evidence from 1 RCT (Keizer et al 1995 1+) that supplementing predominantly white adolescent mothers from low income households with 300 micrograms folic acid/day for 4 weeks (commencing within one week of delivery) prevented a decline in erythrocyte folate levels for the first 3 months of lactation.

10. There is evidence from 1 RCT (Mackey et al 1999 1-) that supplementing lactating women from middle to high income households with 1mg/day folic acid from 3-6 months post partum resulted in significantly higher erythrocyte folate concentrations at 6 months than in controls.

11. There is evidence from two RCT’s (Cross et al 1995; Kalkwarf 1997 both 1-) that supplementing women with calcium during lactation has no beneficial effect on bone mineral density. Loss of bone mineral density in the spine appears to be part of the normal physiological process of lactation and it increases again during weaning. Supplementation with calcium does not appear to have any effect on this process.

Current NICE Grading Scheme


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<td>Case–control or cohort studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal*</td>
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<td>Non-analytic studies (for example, case reports, case series)</td>
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*Studies with a level of evidence 1*- are not to be used as a basis for making a recommendation (see section 7.4)
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| ++                  | All or most of the quality criteria have been fulfilled  
Where they have been fulfilled the conclusions of the study or review are thought very unlikely to alter |
| +                   | Some of the criteria have been fulfilled  
Where they have been fulfilled the conclusions of the study or review are thought unlikely to alter |
| -                   | Few or no criteria fulfilled  
The conclusions of the study are thought likely or very likely to alter |

Source: NICE, 2004
3. Background

This background section has been compiled by the review team, based on material identified in the course of the search (but not included in the review); national reference data on nutritional intakes; and the review team’s own expertise and resources.

The nutrition of new mothers is an important public health subject. Improvement in dietary intake postpartum is likely to have a positive impact on a mother’s health, and may have an impact on her baby’s health, her own health in subsequent pregnancies, and possibly on her future health. Mothers who were disadvantaged in their pre-pregnancy and pregnancy nutrition will be in greater postpartum nutritional need. This may be exacerbated by anaemia and consequent morbidity following blood loss at the birth (MacArthur et al. 1991). For many mothers, the postpartum year will be part of an inter-pregnancy interval, and these women need also to meet preconception nutrition needs at this time.

Around 700,000 women in the UK are within the first postpartum year at any one time, spanning an age range from the mid teens to 40+ (Macfarlane et al. 2000). Challenges they encounter during this year will vary depending on their parity, socio-economic and ethnic background, their health and wellbeing, the health of their baby, whether they breast or artificially fed, and their family circumstances. Whatever their circumstances, all will have to deal with the day to day demands of the care of a new baby while also meeting their own physical and emotional needs.

Consideration of women’s nutritional needs postpartum needs to examine two different perspectives; a) the specific nutrient and micro-nutrient needs of women who have had a baby within the past year, and b) the challenges to eating consequent on having a baby, which can include lack of time, sleeplessness and exhaustion, lack of appetite, low emotional state, lack of money, restricted access to shops, restricted opportunity for physical exercise, and possible ongoing physical problems such as pain and incontinence. We will consider the background to these two perspectives in turn, including current national recommendations where these exist.

3.1. Nutrient needs of postpartum women

Recommended intakes for certain nutrients from the COMA report – Dietary Reference Values for Food Energy and Nutrients for the United Kingdom (DH 1991) are given in Table 1. This gives the recommended dietary intake for women of different ages and additional requirements during pregnancy and lactation. These recommendations are mostly based on data on milk quantity and nutrient composition and on maternal nutrient reserves. As a result of the lack of empirical data, these recommendations reflect a theoretical perspective. The total recommended intake can vary with maternal age, degree of exclusivity of breastfeeding and month post partum as shown by the data for energy and zinc intake. For some nutrients including iron and vitamin B6, no increase is recommended. For other nutrients no specific recommendations for intakes in lactating women have been made and only those for the adult population as a whole are given; for example for total fat, saturated fatty acids, unsaturated fatty acids etc.

The dietary reference values (DRV) in the COMA report (DH 1991) which include an increment for pregnancy and lactation are protein, riboflavin, folate and vitamins A and D. It is suggested that lactating women need additional increments for niacin,
vitamin B12 and the minerals calcium, phosphorus, magnesium, zinc, copper and selenium. Asian women living in the UK were particularly identified as having an increased need for vitamin D if they rarely went out and wore concealing clothes (Department of Health, 1998). A COMA report on the Welfare Food Scheme (2002) noted that there were no national data on diet during lactation, only two small studies in 1986 and 1989 (Black et al. 1986, Schofield et al. 1989).

Average intakes for specific nutrients and UK women in the NDNS survey in 1991 (Hoare et al. 2004) are also given in Table 1. Mean intakes of these nutrients for women generally increased with increasing age except for total fat intake, which showed a slight decrease with increasing age and total energy intake which was lowest for women aged 25-34 y. Saturated fat and total fat intakes were higher than the recommended Reference Nutrient Intake (RNI). Mean total energy intake was 85% of the RNI. Mean folic acid, vitamin B6, calcium and zinc intakes were close to or higher than the RNI for all age groups but the mean intake of iron for all women aged 19-49 y was <70% of the RNI. Women aged 19-24 y also had a mean vitamin B6 intake that was 78% of the RNI.

Such reference values need careful consideration before using to inform practice and policy, however. Nutritional needs are increased during pregnancy and lactation to allow for fetal and infant growth, but there are also alterations in maternal metabolism during these periods. It is not thought likely that the heightened nutritional needs can be met completely from the maternal diet (Picciano et al. 2003). Enhanced needs can be to some extent offset by altered nutrient utilisation and mobilisation of reserves, but sometimes nutrient deficiency can occur, particularly with respect to certain micronutrients that are unevenly distributed in foods. There is a debate about the relative nutritional demands of pregnancy and lactation but some authors believe that nutritive demands for the first four-six months of lactation are considerably greater than those of pregnancy (Picciano et al. 2003).

Few studies have measured actual nutritional status in lactating or non-lactating mothers. One such study of 52 healthy lactating women in Pennsylvania, USA assessed energy and nutrient intakes at three and six months postpartum (Mackey et al. 1998). Mean energy intake was below the RDA; this is not an unusual finding in studies of nutritional intake. Mean intake of most nutrients met or exceeded recommended standards, except for zinc and vitamins C and E at both three and six months postpartum and calcium and folate at six months postpartum. Mean iron intake was sufficient but declined from three to six months. The frequency of low intake increased from three to six months postpartum for calcium, iron, folate and vitamins E, D and B6 and at six months the women in the Pennsylvania study were consuming less than half the RDA for calcium, folate and vitamin B6.

Although the evidence base for infant nutrition now supports exclusive breastfeeding for six months (Kramer and Kakuma 2002), information about the impact on maternal nutritional status is scarce. Lactating mammary glands have a metabolic priority for nutrients, which can be to the expense of maternal reserves (Institute of Medicine 1991). A systematic review which assessed exclusive breastfeeding for six months versus three-four months concentrated on the outcomes for the child (Kramer and Kakuma 2002). The only outcomes for the mother noted were more rapid post partum weight loss and more prolonged lactational amenorrhea. No data were obtained for non-lactating women in this review.
3.2. The challenges to eating consequent on having a baby

Even women who are able to afford and are accustomed to eating a healthy diet face challenges in continuing to do so when they have a new baby. This is especially so for a first baby, but also when the constant demands of care for a new baby are additional to caring for another child or children (Hewison and Dowswell 1994). The baby’s needs are frequent and irregular and meeting them disrupts adult and family eating and sleep patterns. Getting out of the home and staying out for long enough to buy food can be difficult, especially for unsupported women and for women reliant on public transport (Whelan et al. 2002). Changes in how to buy, prepare and eat food whilst caring for the baby have to be worked out and maintained when mothers are sleep deprived and may be exhausted. Change of role and loss of adult company may lead to mothers experiencing emotional difficulties or mental health problems (Brown et al. 1994). Loss of activities that previously structured daily living is disorienting in itself and when a mother was previously in paid employment is likely to entail loss of income. Baby care involves new costs (Macfarlane and Mugford 2000) and less money to spend on food. Such factors may lead to neglect of good nutrition, with proportionately greater effect on unsupported mothers and those in low income households.

Existing unhealthy diet and activity patterns can be exacerbated by childcare demands especially when coupled with fatigue, depression, physical symptoms or social isolation (Peterson et al. 2002). Women experience many health problems postpartum. MacArthur et al. (1991) reported the results of a study of 11071 postpartum women in Birmingham. The most common problems were backache, bladder problems including stress incontinence and urinary frequency, extreme tiredness, haemorrhoids, depression or anxiety and frequent headaches. They were first experienced during the 1st three months postpartum and frequently lasted for more than six weeks. An Australian study (Brown et al. 1994) of postnatal depression in 1193 recent mothers found that ‘the baby blues’ occurring at 3, 4 or 5 days after birth were very common. Clinical depression occurred in about two mothers in every 1,000 and was most common one week to three months post partum. Depression was more likely in women who had had difficult births or unpleasant experiences during the birth or immediately afterwards, especially in hospital and who were not given enough support. Depression was less likely for those who breastfed at birth, were still breastfeeding at three months, aged >34 years, already had children, had good antenatal care or felt confident when leaving hospital.

3.3. Nutrition and inequalities in health

Since the 1980s, additional nutritional issues have been highlighted particularly amongst those on low incomes, but few of these issues have been addressed in relevant studies. Since 1997, the issue of Food Poverty has been placed on the political agenda. The Deputy Head of the Food Standards Agency stated that ‘food poverty is of course a multi-faceted problem. It is partly about sufficient income; it is also about access to shops, knowledge and confidence in food skills, as well as the promotion and advertising of food’ (Leather 2000). The concept of ‘food deserts’ (Whelan et al. 2002) has been introduced and there are concerns about the general predominance of supermarkets in the food market. Conversely, a 1996 study in five British areas found the same basic foodstuffs cost 24% more in small stores than in large supermarkets (Piachaud and Webb 1996). People on low incomes also do not always use local markets which frequently sell local fresh produce at a cheaper price than the supermarkets. Recently, many public recommendations for healthy eating have been made, many by the Food Standards Agency. One of the strongest has been the ‘Five a Day’ message to eat five portions of fruit and/or vegetables per day.
It may not be possible for families on low incomes to follow such recommendations, however. The annual Family Expenditure Survey (Dowler et al. 2001) found that proportionally more of the income was spent on food by lower income groups but despite that the actual amount spent was only £25.50 a week per family for the lowest 10% income group compared to £106.00 for the highest 10% income group in 1999/2000. This was assessed not to be enough to eat healthily (Gordon et al. 1996). There have been consistent findings that parents, particularly mothers, go without in order to protect their children’s diets (Office of National Statistics (ONS) 2001; Dobson et al. 1994; Dowler and Calvert 1995). The new Healthy Start scheme, successor to the Welfare Food Scheme, has been designed in part to try and address such food poverty; food vouchers worth £5.60 weekly will be given to breastfeeding women and to formula fed babies for the first 12 months; thereafter, children will receive £2.80 per week up to age 4.

3.4. Weight gain and weight loss

Weight related issues postpartum, especially for low-income women, include both under- and over-weight, both resulting from inadequate nutritional intake. Most recent literature, however, concentrates on the need for weight loss and the prevention of overweight/obesity. The desire reported by many postnatal mothers to return to their pre-pregnancy weight as soon as possible has been reported as a factor in making infant feeding decisions, but little is known about healthy weight and BMI for postnatal women or how best to achieve these.

A key review of 12 articles (mainly from North America) by Walker et al. 2005 found that at six weeks postpartum, women retained 3-7 kg of the weight gained during pregnancy, with at least two thirds exceeding their pre-pregnant weight. There was a consistent relationship between postpartum retained weight and gestational weight gain (or maternal weight gain, which excludes birth weight) and a less consistent positive link with pre-pregnant BMI, pre-pregnant weight and height. Maternal age, gravidity, parity, gestational length and infant birth weight, infant sex and breastfeeding were consistently not related to retained weight at 6 weeks postpartum. Four of the included studies related postpartum weight loss at six weeks to weight at the end of pregnancy, range ~6.5-9.5 kg (excluding birth weight), which the authors suggested might be preferable.

The American Institute of Medicine (IOM 1990) recommend for normal weight women a midpoint prenatal gain of 13.75 kg, and Walker et al. 2005 predicted an expected retention of 4.75 kg after delivery of the products of conception (5 kg) and early fluid loss and tissue reduction (4 kg) during the first two postpartum weeks. The remaining weight was attributable to fat stores. Overweight non-lactating women are recommended by the National Heart, Lung, and Blood Institute (1998) to lose weight by reducing caloric intake by 300-500 kcal/day with a predicted weight loss of 0.22-0.45 kg/week (i.e. a loss of 4.75 kg would take 11-22 weeks). A UK study by Lawrence et al. in 1991 found fat stores early postpartum were lost at a rate of 0.25 kg/week, implying that the upper estimate of time taken would be more typical.

Caution should be exercised when advising postpartum women about weight loss as other adverse effects may result. For example, strict adherence to a low calorie diet may aggravate existing exhaustion. A further complication for breastfeeding women is that fat soluble contaminants such as dioxins, OCs and PCBs may be mobilised as a result of very low fat diets, releasing those contaminants into the breast milk, and thereby to the baby (Harris et al 2001).
Walker et al. (2005) noted that African American and Hispanic women were less likely than white women to have excessive weight gain during pregnancy yet, during the latter half of the first postpartum year, African American women retained more weight from pregnancy than white women.

Keppel et al. (1993) used data from the American 1988 National Maternal and Infant Health Survey to assess the implications of revised Institute of Medicine (IoM) Guidelines which increased the recommended pregnancy related weight gain. Weight gain 10-18 months postpartum was classified retrospectively using the IoM Guidelines. Weight retention was found to increase as weight gain increased and black women retained more weight than white women. The median retained weight for those who gained the recommended weight was 1.6 lb in white women and 7.2 lb in black women.

Overweight women have been found to have a higher risk of gaining weight after successive pregnancies than lean women or women of normal weight and such gains are retained one year after birth (Rossner 1992). In a UK study of overweight pregnant women in Southampton, the women were generally concerned not to weigh more after the pregnancy than before (Wiles 1998). In the absence of specific advice, they formed their own views about an appropriate weight gain despite being informed about the 'expected' weight gain. The average pre-pregnancy weight was high - 91 kg (BMI range 25-45) yet their average weight six weeks after the birth was 94 kg.

A UK study in Oxford (Stein and Fairburn 1996) of 97 primigravid women found them concerned about their eating, weight and shape three months post partum, but less concerned about eating and shape and more concerned about weight from 3-6 months post partum. The women were therefore most at risk of eating disorders at three months post partum. The mean ± SD pre-pregnancy weight was 58.1±7.69 kg; late pregnancy weight, 70.9±8.54 kg; 3 months post partum weight, 62.0±8.48 kg; and 6 months post partum weight, 59.9±8.82 kg. Therefore the average weight gain in pregnancy was ~12.8 kg, the mean weight loss at three months and six months was 8.9 kg (70% of weight gain in pregnancy) and 11.0 kg (86% of weight gain in pregnancy), respectively.

The Stockholm Pregnancy and Women’s Nutrition (SPAWN) study recently reported on a 15 year follow-up study of the weight effects of pregnancy in 2342 women (Linne et al. 2004). Women who were overweight did not have a higher risk of postpartum weight retention than women with a BMI within the normal range. Both high weight gainers and high weight retainers had a higher BMI at the 15-year follow-up, although only 56% of high weight gainers during pregnancy were high weight retainers at the one-year follow-up. Therefore weight retention at the end of the postpartum year predicted future overweight 15 years later. The tertiles for weight gain during pregnancy were <12 kg, 12-15.6 kg and >15.6 kg and for weight retained (weight 1 year after delivery – pre-pregnancy weight) were <0.2 kg, 0.2-2.2 kg and >2.2 kg. A previous Stockholm study in 1990 found a mean weight gain in pregnancy of 14.1 ± 4.1 kg (mean pre-pregnancy weight 59.5 ± 8.1 kg) and a net mean increase in weight induced by pregnancy after one year of 0.5 kg (allowing for a general increase in weight over time of 0.2 kg) (Ohlin and Rossner 1990).

Similar results to the SPAWN study for high weight during pregnancy gainers and high weight retainers six months postpartum were obtained in an American study of 540 women with follow-up for 8-10 years (mean 8.5) (Rooney et al. 2002). The average weight gain pre-pregnancy to follow-up was 6.3 kg. Gestational gain was divided into 3 categories – low, as recommended, and high - and weight gain at
follow-up was 4.1 kg, 6.5 kg and 8.4 kg for each category of gestational gain, respectively (p=0.01). Recommended weight gain was probably as described above (US Institute of Medicine 1990). Women who had returned to their pre-pregnancy weight at six months postpartum were 2.4 kg heavier at follow-up, whereas those who still retained weight six months postpartum were 8.3 kg heavier than their pre-pregnancy weight at follow-up (p=0.01). Women who breastfed or participated in aerobic exercise also had significantly lower weight gains.

The Mothers’ Overweight Management Study (MOMS) was of 151 postpartum women >18 years with a child <2 years, who were participating in the US Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in low income households (Krummel et al. 2004). Mean weeks postpartum were 30 weeks and 34% were breastfeeding. The women were inactive with a mean BMI of 30.2±6.9 and 91% were white. Group discussion was used to encourage weight management behaviour after which 55% were in the action stage for weight loss, 29% for exercise (3 sessions of 20 min/week), 24% for avoiding high fat foods (Using food labels and low-fat restaurant choice) and 19% for increasing fibre intake.

3.5. Strategies to improve the nutrition of postpartum women

The Maternity Standard of the National Service Framework for Children, Young People and Maternity Services best practice guidance document (DH 2004) advocates the use of health promotion strategies which concentrate mainly on the child, and also, for postpartum women, ‘healthy lifestyles including skills and knowledge of the purchase and preparation of food to form a balanced diet, active lifestyle and the importance of maintaining a healthy weight’ (Peterson et al. 2002). It draws attention to the need to identify and treat maternal postnatal depression, quoting a prevalence of 10-15%.

Possible strategies to improve nutrition in postpartum women include nutrient supplementation, and interventions to promote healthy eating and lifestyle.

3.5.1. Micronutrient supplementation

The effective use of micronutrient supplements will require a) a sound knowledge base of whether and when they should be used, b) evidence about ways of encouraging their use in relevant population groups.

Relevant data for micronutrient supplements are included in Table 1, Dietary reference values for post partum women, and Table 2, Biomarker reference values. At lower than recommended energy intakes, post partum maternal intake of calcium, magnesium, zinc and folate and vitamin B6 may be low (Jensen 1995). In the US, supplementation of 10 μg/d vitamin D has been recommended for lactating women who avoid milk and high vitamin D foods and 2.6 μg/d vitamin B12 for complete vegetarians (Picciano 2003).

In 1991 in the UK, COMA set a reference nutrient intake of 10 μg/d of vitamin D for all pregnant and breastfeeding women (Department of Health 1991). Dietary sources of vitamin D are limited and the main source is skin synthesis on the exposure of the skin to sunlight. However in the UK, there is limited sunlight of the correct wavelength, especially during the winter and in order to achieve this RNI among pregnant and breastfeeding women, supplementation was recommended. In 2007, COMA’s successor, the Scientific Advisory Committee (SACN) confirmed that this still applies (SACN 2007). Women who are particularly at risk of vitamin D deficiency include those who are of South Asian, African, Caribbean or Middle Eastern descent and those who cover their skin when outdoors.
In the UK, pregnant women and those who have a child under 1 year, who are eligible for the ‘Healthy Start’ Scheme (the successor to the Welfare Food Scheme), can obtain supplements of vitamins C, D and folic acid free of charge. Folic acid is of particular importance as up to 50% of pregnancies are unplanned and it is recommended that 400 μg/d folic acid should be taken by all women who are planning a pregnancy and up until the 12th week of pregnancy in order to reduce the risk of neural tube defects such as spina bifida (Department of Health 1992).

3.6. Brief overview of relevant nutrients

A brief overview of the most relevant nutrients, which may be given as supplements or obtained through the diet, is given here:

3.6.1. Iron

Although there is no increased requirement for iron during lactation or pregnancy, this is related to various factors including the fact that non-reproducing women lose iron during menstruation.

The average iron intake for all UK women in the NDNS survey in 1991 (Hoare et al. 2004) was 85% of the Reference Nutrient Intake (RNI) but mean intakes including supplements were well below the RNI for women aged 19-49 years and decreased with decreasing age. The average percentages of the RNI for iron intake excluding supplements for women aged 19-24 y, 25-34 y and 35-49 y were 60%, 62% and 69%, respectively. The NDNS survey excluded pregnant women and did not produce separate data for lactating women.

Typical UK reference ranges for blood analytes for iron status are given in Table 2, which also gives details of the threshold points used in the NDNS survey (Hoare et al. 2004). Eight per cent of all UK women were found to be anaemic i.e. had haemoglobin levels below the WHO lower limit; 16% UK women had low transferrin saturation (<15%); and 11% had low iron stores (<20 μg/L serum ferritin). The younger the UK women, the lower was the iron status, the relative percentages for women aged 19-24 years were 7%, 27% and 16%, respectively. COMA 2002 reported the results of 3 UK studies, which gave the prevalence of anaemia in pregnant women and varied from 2 to 28%. These studies were in Wales, Southampton and Oxford and spanned the years 1970 to 1992. COMA also reported the results of 2 studies of consumption of iron tablets during pregnancy in 1997-1998, which varied from 43% to ≥59%. The report concluded that a small proportion of UK women were affected by iron deficiency anaemia in pregnancy; women in social classes IV and V and those in ethnic minority groups were more likely to be affected; and there was little correlation between iron intake and iron status (as measured by haemoglobin level).

Sixteen percent of US women of childbearing age show evidence of iron deficiency (<15 μg/L serum ferritin) (Institute of Medicine 2001) and in 1996, 29% of low income US women were anaemic (<110 g/L haemoglobin and in 1994-6, 25% of women of child-bearing age did not meet the then RDA of 15 mg/day iron (Agricultural Research Service 1997), indicating the potential for postpartum deficit.

Data from the US National Health and Nutrition Examination Survey (NHANES III) 1988-1994 (Bodnar et al. 2002) indicate a relationship between deprivation and iron status. They found the prevalence of iron deficiency at 0-6, 7-12 and 13-24 months postpartum were 12.7, 12.4 and 7.8% respectively compared with 6.5% among never-pregnant women aged 20-40. Iron deficiency was defined as abnormal values
for ≥2 of 3 iron status measures (<12 μg/L serum ferritin, >1.24 mmol/L free 
erthrocyte protoporphyrin and <15% transferring saturation). The risks of iron 
deficiency among women with a poverty index ratio of ≤130% at 0-6, 7-12 and 13-24 
months postpartum were 4.1 (95%CI: 2.0-7.2), 3.1 (95%CI: 1.3-6.5) and 2.0 (95%CI: 
0.8-4.1) respectively compared with never-pregnant women with a poverty index 
ratio of >130%; but were not elevated when compared to never-pregnant women 
with a poverty index ratio of ≤130%. The risk of iron deficiency was not significantly 
different for post partum women with a poverty index ratio of >130% and never 
pregnant women with the same poverty index ratio. Women were thought to be at a 
lower risk of iron deficiency through the postpartum period since a large proportion of 
the 450 mg iron required for red cell production during pregnancy returns to maternal 
stores when the red cell mass contracts. In addition, the delayed return of menses 
reduces iron losses and little iron is lost in human milk during lactation. Although 
pregnant women and infants are the groups most vulnerable to iron deficiency, it 
seems that postpartum women, particularly those with a low income, may also be at 
high risk.

The Norwegian Board of Health (NBH) in 1995 recommended supplementation of 
30-50 mg/day Fe^{2+} as sulphate or fumarate from week 20 for pregnant women with 
serum ferritin ≤60 μg/L and ≤100 mg/day Fe^{2+} from the 1st antenatal visit for those 
with a serum ferritin <20 μg/L but no supplementation for women with >60 μg/L 
serum ferritin. A Norwegian study (Eskeland et al. 1993) compared the effect of two 
supplements with 27 mg/day Fe, one with and one without haem iron, and concluded 
that haem iron was more effective in preventing the depletion of iron stores after 
birth. A later Norwegian study (Sandstad et al. 2003) used the NBH guidelines 
continuing supplementation postpartum, and compared supplementation in women 
with an initial serum ferritin ≤60 μg/L with either a) 60 mg Fe^{2+} as sulphate or b) 3.6 
mg haem iron and 24 mg Fe^{2+} and found a significantly higher mean serum ferritin in 
the women in group a) at 6 weeks postpartum, who received the higher dose (46.5 
vs. 37.3 μg/L,p<0.05). There was no correlation between serum ferritin levels in early 
pregnancy and at 6 weeks postpartum. Peripartum blood loss was the main 
indicator for iron status at 6 weeks postpartum and, with a large blood loss, iron 
stores did not return to normal in 6 weeks.

A randomised controlled trial in the Czech Republic in 2001 (Mara et al.) of 60 post 
partum women who were not anaemic when recruited at the 35th -39th week of 
gestation (haemoglobin >100 g/L) and who had not taken iron supplements during 
pregnancy, examined three different groups. Two groups took 80 mg/day Fe^{2+} as 
sulphate plus 30 mg ascorbic acid for 0-2 months post partum; one of which also 
took 0.35 mg folic acid; and the control group received nothing. They were followed 
from 0-3 months postpartum. There was a faster adjustment of laboratory and clinical 
indicators of postpartum anaemia in the treated women and adding folic acid 
appeared to have no impact. For example, after one month 15% and 10% in the 
treated groups and 50% in the control group were anaemic whereas after three 
months only one woman (in the control group) was anaemic.

2.6.2 Calcium and bone density
Bone density has been reported to decrease by 4-7% in the lumber spine and hip in 
women who breastfeed for six months (Kalkwarf et al. 1997). Although bone density 
increases after weaning, it is not clear whether it is completely restored. The extent 
to which calcium supplementation minimises bone loss during lactation is not known 
though two studies (Cross et al. 1995; Prentice et al. 1995) have found a minimal or 
no effect. The earlier menses return, the lower the bone deficits. Intestinal calcium 
absorption and renal retention of calcium both increase after weaning.
2.6.3 Docosahexaenoic acid (DHA)
DHA is a long chain omega-3 polyunsaturated fatty acid (PUFA), which is one of the longest chain PUFAs (22 carbon atoms) found in fish oil.

The FSA produced an Annex to a report on fish consumption, ‘DHA requirements in pregnancy and lactation’ (Wootton et al. 2004). The report questioned the ability of mothers to provide adequate amounts of preformed long chain polyunsaturated fatty acids, including DHA (22:6n-3) and eicosapentaenoic acid (EPA, 20:5n-3) for infants and the resulting effects on their own dietary requirements. The current estimate of dietary intakes of DHA in the UK was ~100 mg/d for adult women but was likely to be substantially less for women who did not consume fish, or consume a low fat diet. It was suggested that DHA itself could be an essential dietary constituent and that the maternal requirement for DHA might be as much as 300 mg/d during pregnancy and lactation. Evidence was provided to support the view that prolonged and extensive lactation might be causally related to maternal DHA depletion, particularly when associated with multiple pregnancies. DHA supplementation was shown to increase plasma and breast milk DHA but it was not known if it would ameliorate maternal DHA depletion over successive pregnancies and periods of lactation, which warranted further investigation.

2.6.4 Health promotion in childbearing women
Mothers are the key for establishing healthy eating patterns in the whole family, particularly young mothers. Women themselves recognise that ‘Eating a healthy diet’ is one of the most important things people can do to promote long term good health (Flynn 1996). The time after birth is perhaps especially opportune for interventions to promote healthy eating; most health promoting interventions in women have not specifically targeted lactating or post partum women however, but simply women of childbearing age or pregnant women.

A review of ‘Effectiveness of interventions to promote healthy eating in pregnant women and women of childbearing age’ (Van Teijlingen 1998) defined healthy eating targets as those in line with the National Advisory Committee on Nutrition Education’s (NACNE) 1983 recommendations (Note: these differ from the current COMA/ SACN recommendations):

- A total fat intake of ≤115 g/d (34% total energy) (i.e. a reduction in total fat intake)
- An average intake of ≤50 g/d saturated fatty acids (15% total energy) (i.e. a reduction in saturated fatty acid intake)
- An average intake of ≥18 g/d polyunsaturated fatty acids (5% total energy) (i.e. an increase in polyunsaturated fat intake)
- An intake of ≤30 g/d sucrose (12% total energy) (i.e. a reduction in sugar intake)
- Maintenance of energy intake through low-fat foods, particularly bread, potatoes, fruit and vegetables (i.e. an increase in low-fat food intake)
- An intake of ≥25 g/d dietary fibre (i.e. an increase in fibre intake)
- An intake of ≤1 g/d salt (i.e. a decrease in salt intake)

Of the five studies which used health promotion interventions in this review, only one directly approached a reduction in saturated fat and cholesterol intake (Lagstrom et al. 1999). For the remaining four studies, the main aim was a restriction in energy intake accompanied by an increased physical exercise level. A calorie deficit of -500 kcal was the aim for two studies (Lovelady et al. 2000 and O’Toole et al. 2003), which for the study by O’Toole et al. comprised -350 kcal (70%) by reduced dietary intake and -
150 kcal (30%) by increased exercise. The aim for the study by McCrory et al. 1999 was a net -35% energy deficit with 60% by dietary restriction and 40% by additional exercise. For Leermakers et al. (1998) there was a specific additional aim of a 20% reduction in fat intake and reduced cholesterol. None of these five studies were specifically targeted at low income women. It is recognised that interventions for low-income and/or specific groups of women e.g. multi-ethnic groups need to be specifically developed for those groups (Peterson et al. 2002).

3.7. Conclusion to introduction

In summary, nutrition for postpartum women needs to take into account the demands and changes to their lives, physical, emotional, financial and practical. Changing nutritional behaviour and nutrition-related outcomes is challenging in any field, and it may be that in this field, it is a long-term challenge. In addition to studies of short-term interventions, a life-course perspective may be needed to tackle health inequalities and ‘the cumulative effect of different exposure to health-damaging or health-promoting physical and social environments’ (Variations in Health, DoH Report 1995, Acheson 1998).
### Table 1 - Dietary reference values for post partum women*

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Unit</th>
<th>Age 11-14 y</th>
<th>Age 15-18 y</th>
<th>Age 19-50 y</th>
<th>Pregnancy**</th>
<th>Lactation***</th>
<th>Adult</th>
<th>All women****</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>kcal/d</td>
<td>1845</td>
<td>2110</td>
<td>1940</td>
<td>+200</td>
<td>+240 to 570</td>
<td>85% of DRV</td>
<td></td>
</tr>
<tr>
<td>Total fat</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>34.9</td>
</tr>
<tr>
<td>Total fatty acids</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30</td>
<td>13.2</td>
</tr>
<tr>
<td>Saturated fatty acids</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Cis-polyunsaturated fatty acids</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>n-3</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.2 (minimum)</td>
<td></td>
</tr>
<tr>
<td>n-6</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.6 (minimum)</td>
<td></td>
</tr>
<tr>
<td>Trans fatty acids</td>
<td>% total energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12</td>
<td></td>
</tr>
<tr>
<td><strong>Minerals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td>µmol/day</td>
<td>260</td>
<td>260</td>
<td>260</td>
<td>no increase</td>
<td>no increase</td>
<td>179</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>mg/day</td>
<td>800</td>
<td>800</td>
<td>700</td>
<td>no increase</td>
<td>+550</td>
<td>777</td>
<td></td>
</tr>
<tr>
<td>Zinc</td>
<td>µmol/day</td>
<td>140</td>
<td>110</td>
<td>110</td>
<td>no increase</td>
<td>+40 to 90</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td><strong>Vitamins</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Folate</td>
<td>µg/day</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>+100§</td>
<td>+60</td>
<td>251</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>µg/day</td>
<td>600</td>
<td>600</td>
<td>600</td>
<td>+100</td>
<td>+350</td>
<td>671</td>
<td></td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>mg/day</td>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>no increase</td>
<td>no increase</td>
<td>169</td>
<td></td>
</tr>
<tr>
<td>Vitamin D</td>
<td>µg/day</td>
<td>none</td>
<td>none</td>
<td>none</td>
<td>10</td>
<td>10</td>
<td>2.8</td>
<td></td>
</tr>
</tbody>
</table>

*Dietary Reference Values for Food Energy and Nutrients for the UK, DOH, Stationary Office UK, 1991
**last trimester only
***Depending on month and exclusivity of breast-feeding Zinc - lactating mothers: 0-4 months +90; 4+ months +40 Energy - lactating mothers: 1st month +450; 2nd month +530; 3 month +570; 4-6 months +480 (+570 exclusively breastfeeding); >6 months +240 (+550 breast milk - main source)
§400 µg/day during the 1st 3 months of pregnancy DoH, 1992.
Table 2 - Biomarker reference values

<table>
<thead>
<tr>
<th>Biomarker</th>
<th>Units</th>
<th>Reference range or mean*</th>
<th>Women/adult</th>
<th>NDNS*** Mean values for women 2003</th>
<th>NDNS threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>All women</td>
<td>Age (y) 19-24</td>
</tr>
<tr>
<td>Serum ferritin</td>
<td>µg/L</td>
<td>8-300</td>
<td>women</td>
<td>53</td>
<td>41</td>
</tr>
<tr>
<td>Transferrin saturation</td>
<td>%</td>
<td></td>
<td></td>
<td>26</td>
<td>24.3</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>g/L</td>
<td>115-165</td>
<td>women</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>Plasma iron</td>
<td>µmol/L</td>
<td>10-28</td>
<td>women</td>
<td>16.1</td>
<td>15.6</td>
</tr>
<tr>
<td>Erythrocyte folate</td>
<td>µg/L</td>
<td>&gt;100</td>
<td>adult</td>
<td>685</td>
<td>576</td>
</tr>
<tr>
<td>Plasma folate</td>
<td>µg/L</td>
<td>2-20</td>
<td>adult</td>
<td>22.1</td>
<td>20.6</td>
</tr>
<tr>
<td>Plasma vitamin B6</td>
<td>nmol/L</td>
<td>20-140</td>
<td>adult**</td>
<td>288</td>
<td>247</td>
</tr>
<tr>
<td>Plasma vitamin B12 (as cyanocobalmin)</td>
<td>ng/L</td>
<td>160-925</td>
<td>adult</td>
<td>10.1</td>
<td>9.3</td>
</tr>
<tr>
<td>Plasma linoleic acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma DHA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma EPA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma beta-carotene</td>
<td>µg/L</td>
<td>90-310</td>
<td>adult**</td>
<td>0.304</td>
<td>0.233</td>
</tr>
<tr>
<td>Plasma alpha-carotene</td>
<td>µg/L</td>
<td>14-60</td>
<td>adult**</td>
<td>0.081</td>
<td>0.048</td>
</tr>
<tr>
<td>Plasma lutein and zeaxanthin</td>
<td>µg/L</td>
<td>80-200</td>
<td>adult**</td>
<td>0.29</td>
<td>0.26</td>
</tr>
<tr>
<td>Plasma lycopene</td>
<td>µg/L</td>
<td>100-300</td>
<td>adult**</td>
<td>0.463</td>
<td>0.452</td>
</tr>
<tr>
<td>Plasma Ca</td>
<td>mmol/L</td>
<td>2.12-2.62</td>
<td>adult</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Scottish Trace Element & Micronutrient Laboratory, 2006, http://www.trace-elements.org.uk
3.8. References for Background


4. Methodology

4.1. Literature Search

Julie Glanville and Dave Fox (Centre for Reviews and Dissemination, University of York) conducted the searches for this rapid review in February 2006, with input from the MCN-CC review team (SEK and FM). Initially, a scoping search was undertaken in order to direct and refine the final search strategy. All of the searches were conducted using a stepped approach to identify relevant systematic reviews (SRs), randomised controlled trials (RCTs) and non-randomised studies (cohorts, qualitative studies and surveys). A worldwide search of a number of databases was conducted to identify relevant systematic reviews (from 1995 onwards). Secondly, a worldwide search for randomised controlled trials (RCTs) was conducted (from 1990 onwards). Finally, the search included any type of study – but this search focused on studies from the UK published from 1990 onwards. Studies not published in English were excluded from the review. A detailed report of processes, databases, and search terms used in the review is presented in Appendix C.

The searches for systematic reviews, randomised controlled trials and UK studies identified 213, 3822 and 1068 citations respectively, totalling 5103 citations. The searches were run again in January 2007. A total of 681 additional citations were identified (19 systematic reviews, 526 randomised controlled trials and 136 UK studies). Taking the original and update searches together, 232 systematic reviews, 4348 randomised controlled trials and 1204 UK studies, totalling 5784 citations, were identified. As part of the NICE process, stakeholders and Programme Development Group members are invited to submit additional papers for consideration. For this particular review, no further studies were suggested through this process.

4.2. Selection of Studies for Inclusion

4.2.1. Participants

To be included in the review, the studies had to examine postpartum women living in developed countries from any socio-economic background. Where data was available, the review also considered the following population subgroups:

- Mothers in lower socio-economic groups
- Mothers living in areas of deprivation including inner city areas
- Black and minority ethnic groups
- Mothers aged under 18
- Unsupported mothers
- Mothers from groups who are likely to be nutritionally vulnerable, including those who are homeless, travellers, refugees or asylum seekers, disabled women, prisoners
- Mothers with weight change in pregnancy above or below the normal range
- Mothers with BMI above or below the normal range in pregnancy and/or postnatally.

Studies that included mothers with clinical conditions that required specialist advice, secondary dietary management or clinical therapeutic advice, were excluded from the review. Studies of mothers with multiple births were not excluded.

4.2.2. Interventions

The review included all public health type interventions that aimed to improve the nutrition of postpartum women. Interventions that took place during the first year after birth were included. Interventions that occurred during pregnancy only were not
considered. It must have been possible for the intervention to be delivered by practitioners at the primary care level. Interventions of interest included:

- Food / nutrient supplementation
- Dietary advice/ counselling / education, in particular, aimed at achieving and maintaining healthy postpartum BMI/ weight
- Interventions to deliver dietary advice/ counselling/ education/ supplementation, in particular, interventions aimed to promote folic acid intake/status
- Interventions to improve access to healthy foods
- Interventions to improve relevant nutrition knowledge among practitioners

4.2.3. Outcomes
This review was specifically interested in maternal outcomes. Other reviews will focus on outcomes in babies and children. Any maternal nutrition/health outcome that a mother may experience during the postpartum period was included in this review:

- Anaemia
- Fatigue/exhaustion/tiredness
- Infections e.g. mastitis
- Change in dietary intake
- Change in nutrient and micronutrient intake
- Nutrient status, for example iron status
- Appropriate weight loss/ gain
- Breastfeeding duration

Two reviewers independently screened all 5784 titles and abstracts identified in the literature search. Full paper copies of 16 systematic reviews, 72 RCTs and 4 UK studies were obtained and also independently assessed for inclusion by two reviewers. Any disagreements regarding whether or not a paper met the inclusion criteria was achieved by consulting a third reviewer. A list of excluded studies with reasons for exclusion is presented in Appendix B.

4.3. Quality Appraisal
All of the studies that met the inclusion criteria were critically appraised by two reviewers in accordance with criteria described in NICE (2005). A study was graded using a code ‘++’, ‘+’ or ‘-‘, based on the extent to which the potential sources of bias had been minimised. If there was any discrepancy in a grade given to a study by the two reviewers, the opinion of a third reviewer was sought. Each included non-UK study was assessed to determine its applicability to UK settings. The NICE (2005) criteria and the methodology checklist that was used in this review are presented in Appendix E.

4.4. Key research questions
The research questions for this review were as follows:

1. What diet and/or physical activity programmes effectively aid postpartum weight loss?
2. What is the effectiveness of dietary counselling in improving postpartum nutrition?
3. What methods of delivering supplements in the postpartum period are effective?
4. What supplements effectively improve maternal nutritional status?
4.5. Synthesis
Due to heterogeneity of design among the studies, a narrative synthesis was conducted.

5. Summary of Findings

The research questions for this review were as follows:

1. What diet and/or physical activity programmes effectively aid postpartum weight loss?

2. What is the effectiveness of dietary counselling in improving postpartum nutrition?

3. What methods of delivering supplements in the postpartum period are effective?

4. What supplements effectively improve maternal nutritional status?

Within these broader questions, there were also two objectives:

1) To assess at various stages (e.g. at six months, twelve months, and 2 years postpartum) the effectiveness of interventions during the year after birth.

2) To assess the effectiveness of the means of delivering these interventions, particularly nutrition/dietary advice/promotion currently given to UK women during the postpartum period (e.g. folic acid supplementation) and interventions aimed at promoting a healthy body mass index after pregnancy.

From 5784 titles and abstracts identified in the literature search, full paper copies of 16 SRs, 72 RCTs and four UK studies were obtained. None of the SRs met the inclusion criteria for this rapid review. Of the 72 RCTs, 14 were finally included (published in 18 papers). None of the UK studies reported implementation of an intervention that was also examined in the included RCTs, thus all the non-RCT UK studies were excluded. Citations and reasons for exclusion are listed in Appendix B.

Of the 14 included RCTs, four (reported in five papers) evaluated diet and physical activity programmes delivered during the first postpartum year (Question 1). One study, a 1- RCT (Lagstrom 1999) was identified which was of relevance to Question 2. This study reported the effects on the mothers' diet of a dietary counselling intervention aimed at reducing fat intakes among children. The broader applicability of the study to mothers is uncertain as the original study randomised children. No studies were identified that addressed the effectiveness of delivering supplements in the postpartum period (Question 3). The remaining nine studies (reported in thirteen papers) provided evidence of the effect of micronutrient supplementation on postpartum maternal nutritional status (Question 4).

Twelve of the fourteen RCTs identified by the searches for this review have been graded as 1- studies. In most cases this is due to lack of information on the method of randomisation and in two studies to inadequate randomisation. In other cases, the grading is due to high drop out rates or loss to follow up.
There was a particular dearth of evidence regarding effectiveness of interventions among mothers from socially disadvantaged and vulnerable groups. One study (a 1-RCT by Doyle 2001) investigated the effectiveness of taking a multi-vitamin and mineral supplement and a supplement of docosahexanoic acid among postpartum women from a deprived inner city area of London who had had a live low birth weight baby and were planning a further pregnancy. Another study (a 1+ RCT by Keizer 1995) investigated the effectiveness of providing predominantly white adolescent mothers from low income households with folic acid in the postpartum period.

5.1. **What diet and/or physical activity programmes effectively aid postpartum weight loss?**

Four US RCTs (all 1-) investigated the effectiveness of interventions which aimed to promote postpartum weight loss through diet and/or physical activity (Leermakers 1998, Lovelady 2000, McCrory 1999 and O'Toole 2003). Information on the timing, mode, outcome and follow-up for each of these studies is presented in summary form in Table 3 (more details of the interventions and outcomes are presented in the text below and in the data extraction tables).

**Table 3: Studies on diet and/or physical activity programmes with postpartum women.**

<table>
<thead>
<tr>
<th>Reference</th>
<th>When the intervention was delivered</th>
<th>How the intervention was delivered – and by whom</th>
<th>What effect did the intervention have</th>
<th>When was the effectiveness of the intervention assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leermakers 1998 1-</td>
<td>From mean 8 months postpartum for 6 months</td>
<td>As 2 group sessions (baseline and month 2), 16 lessons with homework by correspondence, and telephone contact from programme staff (1-2 calls per week lasting 5-15 mins) Mailings and phone calls from project staff (University of Pittsburgh School of Medicine, USA)</td>
<td>Postpartum weight loss No effect on energy expenditure, as measured by the Paffenbarger Physical Activity Questionnaire (self-reports of stairs climbed, blocks walked and other recreational activities performed in the past week) was found</td>
<td>At the end of the intervention at mean 14 months postpartum</td>
</tr>
<tr>
<td>Lovelady 2000 1-</td>
<td>10 weeks from 4-14 weeks postpartum</td>
<td>As individualised diet prescriptions (some meals provided), supervision of 4x45 min exercise sessions per week By - not stated- by implication, research staff of Department of Nutrition and Foodservice Systems, University of North Carolina,</td>
<td>Postpartum weight, fat and BMI loss and increase in maximal oxygen consumption increase all greater in intervention group than controls</td>
<td>14 weeks postpartum</td>
</tr>
<tr>
<td>Study</td>
<td>Duration of intervention</td>
<td>Methodology</td>
<td>Weight and fat loss</td>
<td>Postpartum weight loss and activity scores</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>McCrory 1999</td>
<td>11 days with women 8-16 weeks postpartum</td>
<td>As individualised diet prescriptions with all food provided (participants instructed to record any not or any extra food eaten), individualised exercise prescription (self-supervised), and heart rate monitors.</td>
<td>Weight and fat loss greater in diet only and diet and exercise groups than in controls. Time spent exercising greater in diet and exercise group than in diet only or controls. Lean body mass loss appreciable in diet only group and negligible in diet and exercise and control groups.</td>
<td>At the end of the 11 day intervention when women were 11-20 weeks postpartum</td>
</tr>
<tr>
<td>O'Toole 2003</td>
<td>From 13 (mean) weeks postpartum, weekly for first 12 weeks, fortnightly for next 2 months and monthly to 1 year postpartum</td>
<td>As individualised diet and physical activity prescriptions, group educational and strategy sessions, and heart rate monitors.</td>
<td>Postpartum weight loss and activity scores greater in intervention group than in controls.</td>
<td>12 weeks into the intervention 12 months postpartum</td>
</tr>
</tbody>
</table>

Leermakers (1998) (quality rating 1-) compared a behavioural weight loss programme lasting 6 months with written information on healthy eating and exercise but no programme in 90 women who were mean eight months postpartum at the beginning of the intervention. Lactating women were excluded from the study. The intervention consisted of two meetings; 16 correspondence lessons about nutrition, exercise and behaviour change strategies tailored to special needs of new mothers; and phone calls twice a week from project staff about goals and problem solving. Participants (mean age 32 years) were predominantly white, well educated and married. The principal setting for the intervention was women's homes. Energy expenditure was not found to change in either group. There was a significantly higher loss of excess post partum weight among women in the correspondence group compared to women in the control group (p=0.01).

Lovelady (2000 and 2006) (quality rating 1-) evaluated the effect of weight loss in overweight (BMI 25-30 kg/m²) lactating women on the growth of their infants. Forty-eight predominantly white, healthy, sedentary, exclusively breastfeeding women were randomised to a 10-week intervention programme (4-14 weeks postpartum) consisting of an energy intake restriction plus aerobic exercise, or to the control group with no restriction of energy intake and vigorous exercise not more than once a week. For the intervention group energy intake was restricted by 500 Kcal/day to ≥ 1800 Kcal/day, and exercise consisted of 4 supervised 45-minute sessions per week.
of brisk walking, jogging and aerobic dancing at an intensity of 65-80% of maximal heart rate reserve (the women wore heart-rate monitors to confirm they were exercising at this intensity). Six of 27 (22%) of the intervention group and 2/21 (10%) of the control group dropped out; results for these women are not reported. The women who dropped out were significantly heavier before pregnancy (p=0.005) and at the beginning of the study (p=0.05), and had a lower level of cardiovascular fitness (p<0.04). At 14 weeks, study completers in the intervention group had significantly greater mean weight loss and reduction in BMI (p<0.001 for both) and reduction in all measures of skin-fold thickness (p<0.01) than controls. The authors reported that the gains in weight and length of the infants whose mothers were in the diet-and-exercise group were not significantly different from the infants whose mothers were in the control group. They concluded that weight loss of approximately 0.5 kg per week between 4 and 14 weeks postpartum in overweight women who are exclusively breastfeeding does not affect the growth of their infants.

McCrory (1999) (quality rating 1-) evaluated the effects of an 11-day programme of dieting compared to dieting plus aerobic exercise on weight loss, fat mass, body fat and lactation performance in exclusively breastfeeding women 8-16 weeks postpartum. Of 135 eligible women 67 chose not to participate (49.6%). Women not willing to exercise 3 days/week for the month before the study (to prepare in case they were randomly assigned to the group with intensive exercise) were excluded. Sixty-eight predominantly white women were randomised to either a diet group (35% energy deficit diet, n=22), a diet and exercise group (35% energy deficit, 60% by dietary restriction and 40% by additional exercise, n=23) or a control group (no energy restriction and no change to baseline exercise, n=23). Mean pregnancy weight gain of participants was 16 kg, and at baseline, their mean±SD BMI was 25.2±4.2 kg/m². Intervention diets were individualised, with food and multivitamin supplements provided. Exercise was individually prescribed as target heart rate range over time via any aerobic exercise and was self-monitored. Follow-up was 67/68 (98.5%). After 11 days loss of weight (p<0.0001), fat mass (p<0.05), and body fat as % body weight (p<0.05) were all significantly greater in both intervention groups than in the control group. However, the diet only group lost appreciable amounts of fat-free lean body mass (mean 0.7±0.6 kg, 95% CI –0.9, -0.4) whereas the control and diet and exercise groups lost small amounts or gained fat-free lean body mass (mean losses in diet and exercise group 0.0±0.9 kg (95% CI –0.43, 0.38) and in control group 0.2±1.0 kg (95% CI –0.2, 0.6), p=0.003 for diet group vs. both diet and exercise and control groups). The authors reported no significant differences in milk volume, composition and energy output, and infant weight among women in the diet group, the diet plus exercise group or the control group. There was however, a significant interaction between group and baseline percentage body fat, such that in the diet group only, milk energy output increased in larger women and decreased in leaner women.

O'Toole (2003) (quality rating 1-) compared an individualised diet and physical activity programme during the first postpartum year with a single educational session in 40 overweight women 6 weeks to 6 months postpartum. The women were predominantly Caucasian and well educated. The authors reported significantly reduced mean weight loss in the intervention group compared with the control group at 12 weeks and at 1 year (p<0.05 for both). In addition, at 12 weeks and 1 year postpartum the intervention group scored significantly higher on a physical activity score than the control group (p<0.05 for both). However follow-up at 1 year was low at 58%. The authors did not assess outcomes on infant growth or measures of milk production. They did report, however, that at one year postpartum, 70% of those completing the study reported continued breastfeeding.
Strength and applicability of evidence

There is evidence from four RCTs (Leermakers 1998, Lovelady 2000 and 2006, McCrory 1999, O'Toole 2003, all 1-) that diet and exercise programmes can be effective in enabling some postpartum women to lose weight gained during pregnancy. This finding is based on US studies of women not noted to be from disadvantaged groups and who appear to be highly motivated to lose weight.

There is evidence from 2 RCT’s (Lovelady 2000 and 2006, McCrory 1999, both 1-) that a combination of diet and physical activity results in more effective and preferable weight loss than diet alone or physical activity alone.

There is evidence (McCrory 1999, 1-) that physical activity as part of a combined diet and physical activity intervention to promote weight loss, is more effective when frequent and regular, than when vigorous and less frequent.

There is evidence from 2 RCT’s (Leermakers 1998, O’Toole 2003, both 1-) that integrated programmes of activity which support participants in combining diet and regular physical activity in order to promote weight loss in the post partum period are more effective than interventions which provide information alone.

There is evidence from 2 RCT’s (Leermakers 1998, O’Toole 2003, both 1-) that the characteristics of programmes which are effective in enabling some women to lose weight in the post partum period are those which: combine diet and physical activity; include strategies for behaviour change; tailor the intervention to individual or group needs; include some group sessions and written materials; provide ongoing support and contact with programme staff; and are of a sufficient duration to make sustained lifestyle changes.

There is evidence from one RCT (McCrory 1999, 1-) that short term weight loss of 1kg/week achieved through a combination of diet plus physical activity in healthy post partum women has no detrimental effect on milk quantity or quality and does not appear to affect infant weight gain.

A second RCT (Lovelady 2000 and 2006, 1-) combining diet and physical activity in healthy post partum women (BMI 25-30) over a longer time period and resulting in a mean weight loss of 0.5kg/week did not appear to affect infant weight or length. However the study may not have been sufficiently powered to demonstrate such effects.

5.2. What is the effectiveness of dietary counselling in improving postpartum nutrition?

One study conducted in Finland (Lagstrom 1999, 1-) evaluated the effects on mothers of dietary counselling regarding their child’s diet. Information on the timing, mode, outcome and follow-up for this study is presented in Table 4 (more details of the interventions and outcomes are presented in the text below and in the data extraction tables).
<table>
<thead>
<tr>
<th>Reference</th>
<th>When the intervention was delivered</th>
<th>How the intervention was delivered – and by who</th>
<th>What effect did the intervention have</th>
<th>When was the effectiveness of the intervention assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lagstrom 1999 1-</td>
<td>Started when child was seven months old. Intervention provided 1-3 monthly to 2 years old (so at least x 3 by 13 months old), then twice yearly to 5 years old</td>
<td>To individual families by a paediatrician and nutritionist at child health clinics</td>
<td>Changes in dietary fat consumption and serum cholesterol of mothers of intervention group children compared with mothers of control group children</td>
<td>Changes not statistically significant at 13 months (results for 47% of those randomised). Changes were statistically significant at 5 years (results for 30% of those randomised)</td>
</tr>
</tbody>
</table>

Lagstrom (1999) (quality rating 1-) reported results from the Special Turku Coronary Risk factor Intervention Project (STRIP). This was a trial undertaken to reduce children’s exposure to the known environmental atherosclerosis risk factors through dietary counselling. In this study, 1062 children attending well-baby clinics were randomised (not the mothers per se). Families of children aged from seven months to two years were randomised to one to three monthly meetings with a paediatrician and nutritionist (and 6 monthly meetings to age 5 years), or to standard care (i.e. they met the same team twice a year with no detailed input on dietary fats). The intervention included individualised counselling that focused on the child’s diet, aiming to modify their dietary fat composition towards a 1:1:1 ratio of polyunsaturated to monounsaturated to saturated fatty acids, whilst supplying adequate amounts of energy.

This paper reports the effect of the intervention on parents’ consumption of selected foods and nutrients, serum cholesterol and body mass index (BMI). At 13 months postpartum, data were available from 47% of the families randomised. Inter-group differences for these mothers in consumption of butter, margarine and oils were not statistically significant at 13 months. At 5 years when data were available from 30% of the families randomised, mothers of intervention group children used less butter, more margarine and more skim milk than those of control group children (p<0.001). No differences were found in consumption of cereals, fruits, vegetables or berries between the two groups. Mean serum cholesterol was slightly lower among intervention group mothers (p=0.03 for group effect though absolute differences minimal after five years). BMI did not differ between parents of intervention and control group during the study. In addition to the low follow-up rates, the researchers caution that participation in the trial probably had unintended effects on the dietary behaviour of the control group families. Children’s intake of nutrients related closely to that of their parents and the researchers suggest that a child’s transition to family foods is the most appropriate time to modify dietary habits in the whole family.
Strength and applicability of evidence

Evidence from this (1-) study (Lagstrom 1999) suggests that individualised, regularly updated, face-to-face advice for parents about specific fats in their child’s diet may have a secondary effect on maternal intake of fats and maternal cholesterol levels at five years postpartum, but no effect on BMI.

Broader applicability of this evidence to mothers is uncertain because the original study randomised children.

5.3. What methods of delivering supplements in the postpartum period are effective?
No studies were identified in the literature search that addressed the effectiveness of delivering supplements in the postpartum period.

5.4. What supplements effectively improve maternal nutritional status?

5.4.1. Fatty Acids
Two studies examined the effectiveness of fatty acids on maternal outcomes. One of the studies was conducted in the USA (Jensen 2000), and the other in Norway (Helland 1998).

Jensen 2000 (quality rating 1-) compared docasahexanoic acid (DHA) supplementation via an algae-produced triacyl glycerol with a high DHA content, two eggs per days with a high DHA content, and low-eicosapentaenoic acid (EPA), high DHA fish oil and two regular eggs per day. No significant differences in total saturated or total monounsaturated fatty acid levels in maternal plasma phospholipids were found. The main aim of the paper however, was to determine the effect of supplementation on the content of breast milk and not the health of the mother.

Helland (1998) (quality rating 1-) examined the effects of cod liver oil compared to no supplementation on breast milk fatty acid composition. While statistically significant increases in maternal plasma DHA and EPA were observed, the focus of this study was composition of breastmilk for babies.

Strength and applicability of evidence

There is evidence from two RCT's (Jensen 2000, Helland 1998, both 1-) that supplementing mothers up to the eighth week post partum with supplements of docasahexanoic acid (DHA) from a variety of sources increases the amount of DHA in maternal plasma and in breast milk in a dose dependent manner.

5.4.2. Multi-vitamin and fish oil supplements
Doyle (2001) (quality rating 1-) examined whether micronutrient supplementation improved the nutritional status of mothers with low-birthweight babies and poor diets during the inter-pregnancy interval. This was part of a larger study of women living in a deprived inner city area of London who were mothers of low-birthweight babies and intended to have further pregnancies. Thirty-four English-speaking mothers found to have a diet meeting fewer than four of sixteen dietary reference values were randomised to daily multivitamin-mineral and docasahexanoic acid (fish oil) supplements from 3 to 9 months postpartum with advice (intervention group n=17) or
advice only (control group n=17). Analysis included only those who completed the study. Six mothers in the intervention group (35%) did not like the supplements; results from these and from one mother who dropped out of the control group are not reported. There were inter-group differences among those who completed the study. The control group included all of the teenagers as well as more older and white women and more mothers of small and premature babies. For those who completed the study, at nine months postpartum, mean serum folate was 12.5nmol/l in the intervention group and 5.57 nmol/l in the control group (p<0.001), mean erythrocyte folate was 346 nmol/l and 255 nmol/l (p=0.009) and mean serum ferritin 36.0μg/l and 25.4μg/l respectively (p=0.034). Differences in mean haemoglobin (12.6g/dl vs. 13.1g/dl) were not statistically significant.

Strength and applicability of evidence

The effect of this (1-) study (Doyle 2001) demonstrates that multivitamin-mineral and fish oil supplements (that included iron and folate) were effective in raising blood levels of iron and folate in postpartum women who were found to have a diet meeting fewer than four out of sixteen dietary reference values. This study is directly applicable to UK mothers with poor diets.

5.4.3. Iron

Krafft (2005) (quality rating 1++) examined the effects of postpartum iron supplementation with 80mg/day of oral iron sulphate from 24-28 hours after delivery in non-anaemic iron-deficient women. Blood loss at delivery was greater in the control group and haemoglobin estimation may have taken place only 24 hours after delivery, possibly leading to overestimation of postpartum haemoglobin especially in the control group. At 12 weeks, compared with controls (n=24) the intervention group (n=28) had significantly increased ferritin (p=0.0004), transferrin saturation (p=0.03), decreased soluble transferrin receptors (p=0.02), increased haemoglobin (P=0.02) and decreased hypochromic red cells (P=0.04), with no differences in other red cell or reticulocyte parameters. Clinical importance of these findings is unclear.

Mara (2001) (quality rating 1-) randomised ninety women in the third trimester of pregnancy into three groups, to receive either 80 mg of elemental iron per day, or 80 mg elemental iron plus 0.35 mg folic acid per day, or no medication, for two months after the birth. Haemoglobin levels were significantly higher for both treated groups compared with control group during the first (p<0.0001) and second month, but were not significantly different in the third month.

Strength and applicability of evidence

There is evidence from two RCT’s (Kraft 2005 (1++), Mara 2001 (1-)) that supplementing women with iron from early in the post partum period for at least two months can significantly increase levels of haemoglobin compared to non-supplemented controls.

5.4.4. Folic acid

Keizer (1995) (quality rating 1+) assessed the impact of lactation on folate status and ingestion of a low dose postpartum folic acid supplement (300 μg/capsule folic acid per day for 4 weeks, starting within 1 week of delivery) on maternal folate and zinc status and milk composition in adolescent mothers. Biochemical indices measured in the 29 adolescent, predominantly white participants at 4 and 12 weeks did not differ between treatment groups. Average erythrocyte folate concentrations for all groups were well above cut-off value (368nmol/L) indicative of folate depletion. At four
weeks postpartum erythrocyte folate in the supplemented group was significantly higher than in the control group (p<0.05). There was a significant decline (p<0.05) in erythrocyte folate from 4 to 12 weeks in the control group that was not seen in the supplemented group.

**Strength and applicability of evidence**

There is evidence from 1 RCT (Keizer 1995, 1+) that supplementing predominantly white adolescent mothers from low income households with 300 micrograms folic acid/day for 4 weeks (commencing within one week of delivery prevented a decline in erythrocyte folate levels for the first 3 months of lactation.

Mackey (1999) (quality rating 1-) examined the effect of 1 mg/day supplemental folic acid from 3-6 months postpartum on maternal folate status during extended lactation. 42 lactating women took part in the study and their overall dietary intake of folic acid was 380 μg/d. Significantly increased erythrocyte folate (p<0.05) and haemoglobin (p<0.02) and an inverse relationship between plasma folate and plasma homocysteine (p<0.01) were found in the intervention group compared with controls. The researchers conclude dietary folate needs during lactation are probably greater than previously estimated.

**Strength and applicability of evidence**

There is evidence from 1 RCT (Mackey 1999, 1-) that supplementing lactating women from middle to high income households with 1mg/day folic acid from 3-6 months post partum resulted in significantly higher erythrocyte folate concentrations at 6 months than in controls.

5.4.5. **Calcium**

Cross (1995) (quality rating 1-) examined the effects of lactation and supplementation with 1g/day of calcium on bone remodelling. At baseline, mean calcium intake for both groups (total 22 participants) was greater than current US recommended daily allowance (1200 mg/day). A range of changes related to lactation and weaning was seen, but no inter-group differences were found for the indicators of bone remodelling measured. The researchers concluded that an increase in markers of bone turnover and a loss of bone mineral density of the spine during lactation appear to be part of the physiological changes of lactation and are not prevented by increasing calcium intake above the recommended daily allowance.

The calcium supplementation study undertaken by Kalkwarf and colleagues is reported in four included papers (Kalkwarf 1997, Kalkwarf 1998, Kalkwarf 1999, Wosje 2004). Three hundred and eight three women were randomised to 1g calcium/day or placebo. 196 were studied from 2 weeks to 6 months postpartum (lactation study); half of these were lactating and half were not. 187 were studied from 6-12 months postpartum (weaning study); half of these weaned their babies from the breast during this time and the other half had not breastfed since at most 2 weeks after delivery.

Kalkwarf (1997) (quality rating 1-) investigated whether calcium supplementation prevented bone loss during lactation or augmented bone gain after weaning. They concluded supplemental calcium does not prevent total body bone mass loss during lactation and does not benefit lactating women more than non-lactating women, and that bone density increases after weaning both in women who receive calcium
supplementation and in those who do not. To assess the applicability of these findings in the UK, they 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.

Kalkwarf (1998) (quality rating 1-) investigated the effect of long-term calcium supplementation on iron status of postpartum women and described the effects of lactation and weaning on maternal iron status. No significant differences between the calcium-supplemented and placebo groups were found for any outcome measure. A range of effects of lactation on iron status were seen, however calcium supplementation did not appear to interfere with iron status among postpartum women.

Kalkwarf (1999) (quality rating 1-) reports effects of calcium supplementation on calcium homeostasis and bone turnover among the 313 white women included in the main study. The analysis was limited to white women because of known racial differences in renal calcium handling. The overall conclusion of these researchers is that calcium intake between ~750-1700mg/day in Caucasian adult women breastfeeding a single infant has little effect on lactation-induced changes in the calcium economy.

Wosje (2004) (quality rating 1-) examined the effect of calcium supplementation on loss of fat mass during lactation and after weaning, and whether lactation enhanced loss of fat mass. They found body composition changes occurred differently in lactating and non-lactating women during the first 6 months postpartum and occurred at some sites until 12 months regardless of previous lactation status, but overall weight and fat loss was not significantly different between lactation groups. Calcium supplementation had no significant effect on postpartum fat loss at any time point. Their advice that clinicians should use caution when advising mothers about expected rates of postpartum fat loss could be applied in the UK.

Strength and applicability of evidence

There is evidence from two RCT’s (Cross 1995, Kalkwarf 1997, both 1-) that supplementing women with calcium during lactation has no beneficial effect on bone mineral density. Loss of bone mineral density in the spine appears to be part of the normal physiological process of lactation and it increases again during weaning. Supplementation with calcium does not appear to have any effect on this process.

5.5. Sub-questions

Where available, information from the included studies on diet and physical activity were extracted to address the following sub-questions (presented in Tables 5 and 6):

1) How does the structure and content of the intervention influence effectiveness?

Based on the studies of diet and exercise programmes, short, intensive, closely supervised interventions demonstrate significant short-term effectiveness, but longer-term effectiveness was not reported (McCrory 1999, Lovelady 2000). One study of a longer-term, less intensive intervention reports significant effectiveness in both the short and long term (O’Toole 2003). However, there were high drop out rates by the end of the study. Another study of a longer-term, less intensive intervention (Leermakers 1998) did not report short-term outcomes and had similarly high dropout rates by the end of the study. Overall, interventions that enabled women to increase
their physical activity as well as reduce caloric intake were more effective than diet-
only interventions.

2) Does effectiveness vary by gender, age, ethnicity, religious practices or
social/professional group of those receiving or delivering the intervention?

The four studies of diet and exercise programmes provide evidence from 246
predominantly white US women ~30y. Evidence from other women is lacking.

3) Does effectiveness vary with site/setting or intensity/duration of the intervention?

Settings were mainly participants’ homes or places of exercise (unspecified).
Information on other settings is lacking. Short, intensive, closely supervised
interventions demonstrated short-term effectiveness but these studies did not report
longer-term outcomes.

4) What are the views of those receiving and delivering the intervention?

Women’s views were not reported in any of the studies. However, dropouts tended
to be women with more weight to lose. Researchers delivering these interventions
expressed concerns about dropout rates.

5) Is there evidence of unintended or harmful effects?

Only one possible harmful effect was reported. In the study by McCrory (1999),
intensive dieting without increased physical activity led to loss of lean body mass.

6) Are there barriers to replication of effective interventions?

Two longer-term interventions as presented in O’Toole (2003) and Leermakers
(1998) are possibly suitable for replication in UK postpartum women. An intervention
study that involves both increased physical activity and reduced energy intake could
be adapted for use in the UK by existing voluntary sector postnatal support or weight
loss organisations, as well as in postnatal support groups organised by health care
professionals. However, childcare, costs, timing, access, space, and equipment are
among the potential barriers that would need to be addressed.
### Table 5: Sub-questions for studies on diet and exercise interventions

<table>
<thead>
<tr>
<th>Reference</th>
<th>How does the structure and content of the intervention influence effectiveness?</th>
<th>Does effectiveness vary by gender, age, ethnicity, religious practices or social/professional group of those receiving or delivering the intervention?</th>
<th>Does effectiveness vary with site/setting or intensity/duration of the intervention?</th>
<th>What are the views of those receiving and delivering the intervention?</th>
<th>Is there evidence of unintended or harmful effects?</th>
<th>Are there barriers to replication of effective interventions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>O'Toole 2003</td>
<td>Provided intervention group with support to implement diet and exercise information. Increased physical activity appears to have been the programme component that contributed most to weight loss.</td>
<td>Participants (n=40) were predominantly white, well-educated women ~30y</td>
<td>Participants’ own sites/ settings for diet and exercise Setting for meetings not reported Duration to 1 year postpartum</td>
<td>Researchers disappointed by dropout rate (43% dropout at 12 months) Their attempts to ask women’s reasons for dropout were unsuccessful.</td>
<td>None known to be harmful are reported</td>
<td>Researchers suggest child care and return to work.</td>
</tr>
<tr>
<td>Lovelady 2000</td>
<td>Made healthy eating easier and exercising much easier, for 10 weeks</td>
<td>Participants (n=48) were predominantly white women ~30y</td>
<td>Own settings for diet though some meals provided Setting for supervised exercise not reported Duration 10 weeks</td>
<td>Not reported</td>
<td>None known to be harmful are reported. In particular, weight and length of infants were not affected</td>
<td>The current format of this research intervention requires provision of food and a high level of supervision. It might be adapted for use in other settings among women who want to and can commit to a fairly intensive weight loss programme early in the postnatal period.</td>
</tr>
<tr>
<td>Study</td>
<td>Design and Intervention Details</td>
<td>Participants (n)</td>
<td>Setting</td>
<td>Women’s Views</td>
<td>Outcomes</td>
<td>Notes</td>
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<tr>
<td>McCrory 1999</td>
<td>The diet intervention made strict control of dietary intake much easier, for 11 days (exercise though prescribed was self-monitored)</td>
<td>Participants (n=68) were predominantly white women ~30y</td>
<td>Own settings for diet though all food provided</td>
<td>Women’s views not reported</td>
<td>The diet only group lost appreciable lean body mass (mean 0.7±0.6 kg, 95% CI – 0.9, -0.4), significantly greater (p=0.003) than diet and exercise group (0.0±0.9 kg, 95% CI –0.43, 0.38) and controls (0.2±1.0 kg, 95% CI –0.2, 0.6)</td>
<td>This is a research intervention, not meant for replication in other settings</td>
</tr>
<tr>
<td>Leermakers 1998</td>
<td>Provided intervention group with support to implement diet and exercise information</td>
<td>Participants (n=90) were predominantly white, well-educated women ~30y</td>
<td>Setting for 2 meetings not reported</td>
<td>Women’s views not reported</td>
<td>None known to be harmful are reported</td>
<td>Researchers suggest that although the postpartum year may be an effective time period for a weight loss intervention, it may not be a convenient and appealing one for new mothers – it may be a particularly difficult time to make lifestyle changes. Also further pregnancy may occur</td>
</tr>
<tr>
<td>Reference</td>
<td>How does the structure and content of the intervention influence effectiveness?</td>
<td>Does effectiveness vary by gender, age, ethnicity, religious practices or social/professional group of those receiving or delivering the intervention?</td>
<td>Does effectiveness vary with site/setting or intensity/duration of the intervention?</td>
<td>What are the views of those receiving and delivering the intervention?</td>
<td>Is there evidence of unintended harmful effects?</td>
<td>Are there barriers to replication of effective interventions?</td>
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<tr>
<td>Lagstrom 1999</td>
<td>Attrition from child health clinics among families not enrolled in the study would give an indication of effectiveness of structure but is not reported. Focus on dietary fats was narrow, specific and measurable, and focus on prevention of CHD in their child likely to motivate parents, so content of this intervention likely to enhance effectiveness.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>None known to be harmful are reported</td>
<td>This intervention took 5 years to show effectiveness for 30% of those randomised. Priority in the UK for content of such an intervention would need careful consideration given this level of likely effectiveness, and might not be dietary fats only. An intervention with this structure could be delivered in UK child health clinics if staff time were allocated to it.</td>
</tr>
</tbody>
</table>
6. Overview and Discussion

The evidence base presented in this rapid review has some key limitations. Only one of the 14 included studies (Doyle 2001) was undertaken in the UK. Only two studies (Doyle 2001 and Keizer 19950 reported an intervention designed for participants from a vulnerable group. No studies looked at interventions with mothers to promote eating healthier diets. In addition, no studies where the intervention took place both in pregnancy and after the birth were identified. A further limitation of this review, which was specifically interested in outcomes in the mother, is that effects on the child of interventions to promote maternal health and nutrition were not considered in detail. This may be particularly relevant to interventions that promote postpartum weight loss (Harris, Woolridge and Hay 2001, see Introduction to this review).

Overall, four studies provide a body of 1- evidence that diet and exercise interventions can be effective in enabling some postpartum women to lose weight gained during pregnancy. However, women who declined participation or withdrew from these studies tended to be those with most weight to lose. The four studies all took place in the US among predominantly white women who were not noted to be from disadvantaged groups. These studies would appear to be directly applicable to similar relatively advantaged women in the UK.

The most methodologically rigorous of the four studies that examined diet and exercise (McCrory 1999) aimed to establish safety of faster weight loss than currently recommended by the (US) Institute of Medicine. They quote the (US) Institute of Medicine (1991)\(^1\) as stating that for overweight lactating women, weight loss of up to 0.5 kg per week appears safe. McCrory (1999) concluded that short-term weight loss twice that level (Institute of Medicine 1991) appeared safe in their study, with weight loss through a combination of diet and exercise preferable to weight loss by diet alone (since this was found to reduce maternal lean body mass). The authors stress that this may not apply for longer periods of weight loss or to thinner women.

In addition to McCrory (1999), O’Toole (2003) also provides evidence to suggest that diet and exercise together lead to greater weight loss than dietary restriction alone. Lovelady (2000) did not compare these variables together, and Leermakers (1998) did not report data for increased physical activity.

There are two studies that may be applicable to settings and populations in the UK (O’Toole 2003 and Leermakers 1998). However, intervention strategies in both studies did require some staff input. For example, in the study by O’Toole (2003), the intervention involved meetings throughout the postpartum year. Similarly, Leermakers (1998) involved telephone support by project staff twice a week for six months. These types of interventions would be more applicable than those of Lovelady (2000) or McCrory (1999) where staff input included providing food for participants and supervising exercise.

Two of the studies included in the review examine the effects of interventions in the short term only (McCrory 1999 and Lovelady 2000). These shorter, more intense and closely supervised interventions demonstrated short-term effectiveness but these studies did not report longer-term outcomes. The studies that examine the effects of

---

interventions in the longer term (O’Toole 2003 and Leermakers 1998) demonstrate effectiveness for those who remain in the programme, but have high drop out rates.

Fundamental difficulties with implementation not mentioned in the papers include childcare for mothers taking any exercise, and accessibility and costs of organised exercise outside the home.

One study included in this review examined advice to parents regarding their children’s dietary fat intake (Lagstrom 1999). The incidental findings in this study suggest that children’s intake of nutrients is closely related to that of their parents. The suggestion that a child’s transition to family foods is the most appropriate time to modify dietary habits in the whole family could be tested in the UK. The focus of such a UK intervention might be wider than dietary fats only, encompassing more elements of healthy diets. Individualised sessions, as part of regular well baby and child assessments, could be part of the normal work of health visiting and Sure Start teams. This topic overlaps and belongs more properly with other rapid reviews in this series that address children’s nutrition.

One study that examined micronutrients specifically focused on disadvantaged UK women (Doyle 2001). While the study demonstrated significantly increased levels of some micronutrients in the intervention group, the effect is likely to be overstated because of a high dropout rate, imbalanced sample and lack of intention to treat analysis. The study does demonstrate clear dietary needs in a population of poorly nourished mothers of low birthweight babies intending to have further pregnancies and living in a socio-economically deprived area of London.

Doyle (2001) emphasises the practical difficulty of assessing what nutrients are lacking in the women they studied. They suggest women in similar populations who have had a small baby and plan further pregnancies may benefit from routine folate and iron supplementation, and from increased consumption of fortified breakfast cereals. The authors found mothers in their study population did not appear to be receptive to the dietary and lifestyle advice they were offered. They recommend interdisciplinary research into effective methods of improving nutritional intakes of socially disadvantaged populations.

There is a dearth of good quality evidence in relation to many of the questions that matter to postpartum women, especially those from low income groups. In spite of the scale of the problem, and the potential for real benefit not only for the women but also for their families, effective ways of addressing the practical and emotional problems that restrict women’s nutritional intake following the birth of a baby remain unclear. Studies of nutritionally vulnerable women are scarce.

A major change in policy has recently taken place with the introduction of Healthy Start which replaces the longstanding Welfare Food Scheme. It will be important to evaluate the uptake and impact of this programme, especially among specific sub-groups such as very young mothers, and those from minority ethnic groups.

It will be important to consider not only short-term interventions in future studies, but also to take a life-course perspective, and to examine ways of improving nutrition and nutrition-related outcomes for future generations.
APPENDIX A – Included Studies


### APPENDIX B – Excluded Studies

#### Papers excluded

<table>
<thead>
<tr>
<th>Paper – Systematic Reviews</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Couto de Oliveira MI, Bastos Camacho LA, Tedstone A. Extending breastfeeding duration through primary care: a systematic review of prenatal and postnatal interventions. <em>Journal of Human Lactation</em> 2001;17,4:326-343.</td>
<td>Breastfeeding duration is the only outcome. This outcome is the topic of another Rapid Review being undertaken concurrently by our team for NICE</td>
</tr>
<tr>
<td>Lewin GA, Schachter HM, Yuen D, Merchant P, Mamaladze V.</td>
<td>Participants were</td>
</tr>
<tr>
<td>Study</td>
<td>Reason for Exclusion</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>De Vriese SR, Christophe AB, Maes M.</td>
<td>Lowered serum n-3 polyunsaturated fatty acid (PUFA) levels predict the occurrence of postpartum depression: Further evidence that lowered n-PUFAs are related to major depression. Life Sciences 2003;73:3181-3187.</td>
</tr>
<tr>
<td>Reference</td>
<td>Relevant Outcomes</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Makrides M, MA Neumann, Gibson RA. Effect of maternal docosahexaenoic acid (DHA) supplementation on breast milk composition. European Journal of Clinical Nutrition 1996;50:352-357.</td>
<td>The objective of this paper is to establish a relationship between dietary and milk DHA.</td>
</tr>
<tr>
<td>McCrory MA. Does dieting during lactation put infant growth at</td>
<td>Not an RCT</td>
</tr>
<tr>
<td>Reference</td>
<td>Not an RCT</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Moser-Veillon PB. Zinc needs and homeostasis during lactation. <em>Analyst</em> 1995;120:895-897.</td>
<td>Not an RCT</td>
</tr>
</tbody>
</table>

Paper – UK Studies

Reason for Exclusion


**Papers obtained following the update search and excluded**

<table>
<thead>
<tr>
<th>Studies</th>
<th>Reason for exclusion</th>
</tr>
</thead>
</table>

**Randomised Controlled Trial**

APPENDIX C — Search Strategy

Searches for NICE Rapid Review ‘The effectiveness of public health interventions to improve the nutrition of postpartum women’.

Julie Glanville and Dave Fox

Stage I – Scoping
The scoping exercise was a three-stage process:

<table>
<thead>
<tr>
<th>A. Search for systematic reviews in CDSR and DARE (1995 onwards)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. English language</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Search for RCTs in MEDLINE (1990 onwards)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. English language</td>
</tr>
<tr>
<td>b. Developed world</td>
</tr>
<tr>
<td>c. Humans</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. Search for all study designs in MEDLINE for UK (1990 onwards)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. English language</td>
</tr>
<tr>
<td>b. UK</td>
</tr>
<tr>
<td>c. Humans</td>
</tr>
</tbody>
</table>

The searches were difficult to focus, as it is not possible to focus well on maternal nutrition and exclude both child nutrition and the effects of maternal nutrition on the child.

The results are attached:

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic reviews 19</td>
</tr>
<tr>
<td>RCTs focused by using outcome terms 104</td>
</tr>
<tr>
<td>RCTs unfocused 422</td>
</tr>
<tr>
<td>Other study designs (UK) excluding RCTs already found 136</td>
</tr>
</tbody>
</table>

A. Search for systematic reviews in CDSR and DARE (1995 onwards)

This search used the CRD admin database (Cairs B), which contains DARE records, and CDSR abstracts. The search used a combination of MeSH subject headings and text searches. The search is focused on ‘population’ and ‘interventions’. The search located 35 systematic reviews, 16 of which were sifted as definitely not relevant, leaving 19.

1. S mothers /kwo
2. S postpartum period /kwo
3. S postpartum
4. S post-partum
5. S post (w) partum
6. S new (w) mother$
7. S postnatal
A search was carried out of the Turning Research into Practice (TRIP) database, but no additional systematic reviews to those found on CDSR and DARE were located.
B. Search for RCTs in MEDLINE (1990 onwards)

This search used MeSH headings for countries in Africa, Asia and South America to achieve a partial exclusion of abstracts about developing countries. The search was limited to RCTs by using the pragmatic approach of restricting to records with the Publication Type RANDOMIZED CONTROLLED TRIAL. The focused search combines three aspects of the topic:

MOTHERS and INTERVENTIONS AND OUTCOMES

1. Maternal Nutrition/ (199)
2. postpartum period/ or (mother or mothers or maternal or postpartum).ti,ab. (168795)
3. mothers/ or single parent/ or surrogate mothers/ or single-parent family/ (14723)
4. (diet or dietary or nutrition or (vitamin adj d) or (folic adj acid) or food supplement$ or nutrient supplement$ or healthy food$ or healthy eating).ti,ab. (239406)
5. nutritional requirements/ or exp food/ or folic acid/ or exp diet/ (508169)
6. nutrition/ or nutrition policy/ or food habits/ (36354)
7. exp africa/ or exp caribbean region/ or exp central america/ or exp latin america/ or exp south america/ or exp asia/ (426268)
8. DEVELOPING COUNTRIES/ (45261)
9. randomized controlled trial.pt. (208988)
10. fruit/ or vegetables/ (17659)
11. food labeling/ or feeding behavior/ or energy intake/ (41422)
12. communication/ or health education/ or "health knowledge,attitudes,practice"/ or patient education/ or health promotion/ (157129)
13. or/2-3 (174154)
14. or/4-6,10-12 (812043)
15. 13 and 14 (22950)
16. 1 or 15 (23016)
17. or/7-8 (442740)
18. 16 not 17 (19369)
19. 18 and 9 (710)
20. limit 19 to (humans and english language and yr="1990 - 2006") (526)
21. zinc/bl or choline deficiency/ or weight gain/ or weight loss/ or obesity/ (81668)
22. (improved nutrition or better nutrition).ti,ab. (353)
23. (bmi or weight gain or weight loss or anemi$ or anaemi$ or fatigue or tiredness or exhaust$ or infection$ or mastitis or iron status).ti,ab. (691758)
24. Body Mass Index/ (26466)
25. Anemia/ (19823)
26. FATIGUE/ (9755)
The unfocused search combines only two aspects of the topic:

MOTHERS and INTERVENTIONS

The results file excludes the 104 RCT records.
C. Search for all study designs in MEDLINE for UK (1990 onwards)

This search focuses in on UK studies by using the appropriate MeSH headings and a range of country terms in the ‘Institution of the author’ field. The search is focused on ‘outcomes’ but not limited by study design (except for the removal of the RCT records).

1 Maternal Nutrition/ (199)
2 postpartum period/ or (mother or mothers or maternal or postpartum).ti,ab. (172997)
3 mothers/ or single parent/ or surrogate mothers/ or single-parent family/ (14723)
4 diet or dietary or nutrition or (vitamin adj d) or (folic adj acid) or food supplement$ or nutrient supplement$ or healthy food$ or healthy eating).ti,ab. (246107)
5 nutritional requirements/ or exp food/ or folic acid/ or exp diet/ (508169)
6 nutrition/ or nutrition policy/ or food habits/ (36354)
7 exp africa/ or exp caribbean region/ or exp central america/ or exp latin america/ or exp south america/ or exp asia/ (426268)
8 DEVELOPING COUNTRIES/ (45261)
9 randomized controlled trial.pt. (209041)
10 fruit/ or vegetables/ (17659)
11 food labeling/ or feeding behavior/ or energy intake/ (41422)
12 communication/ or health education/ or "health knowledge,attitudes,practice"/ or patient education/ or health promotion/ (157129)
13 or/2-3 (178356)
14 or/4-6,10-12 (818744)
15 13 and 14 (23224)
16 1 or 15 (23290)
17 or/7-8 (442740)
18 16 not 17 (19643)
19 18 and 9 (710)
20 limit 19 to (humans and english language and yr="1990 - 2006") [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained] (526)
21 zinc/bl or choline deficiency/ or weight gain/ or weight loss/ or obesity/ (81668)
22 (improved nutrition or better nutrition).ti,ab. (371)
23 (bmi or weight gain or weight loss or anemi$ or anaemi$ or fatigue or tiredness or exhaust$ or infection$ or mastitis or iron status).ti,ab. (710984)
24 Body Mass Index/ (26466)
25 Anemia/ (19823)
26 FATIGUE/ (9755)
27 MASTITIS/ (2200)
28 Anemia, Iron-Deficiency/ (2821)
29 Iron/df [Deficiency] (2704)
30 or/21-29 (794715)
31 20 and 30 (104)
32 18 and 30 (2860)
33 limit 32 to english language (2575)
34 limit 33 to humans [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained] (1803)
35 limit 34 to yr="1990 - 2006" (1437)
36 exp great britain/ (203886)
37 (united kingdom or uk or wales or scotland or england or ireland or great britain).in. (510137)
Stage II

A. Searches to find systematic reviews

A proportion of the studies identified in the scoping searches were checked manually for relevance. Relevant studies identified were checked for additional relevant textwords and indexing terms, and the search strategy was revised to reflect those terms. Search strategies used varied depending upon the search interface of each source, but an ‘unfocused’ (i.e. omitting outcomes) approach was used to try and ensure all relevant studies were captured. The search was limited to studies in English, and from 1995 onwards.

The following sources were searched:

<table>
<thead>
<tr>
<th>Source</th>
<th>Results</th>
<th>Added to Endnote library (stage 2 maternal nutrition.enl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDSR</td>
<td>49</td>
<td>49</td>
</tr>
<tr>
<td>DARE</td>
<td>93</td>
<td>93</td>
</tr>
<tr>
<td>HTA</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>NRR</td>
<td>270</td>
<td>270</td>
</tr>
<tr>
<td>SIGN</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>National Guideline Clearinghouse</td>
<td>231</td>
<td>2</td>
</tr>
<tr>
<td>NCCHTA</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NICE website</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>HSTAT</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>ReFeR</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>TriP</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HEBW</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Clinical Evidence</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>431</strong></td>
<td></td>
</tr>
<tr>
<td>Following de-duplication and review</td>
<td></td>
<td><strong>218</strong></td>
</tr>
</tbody>
</table>

1. Cochrane Database of Systematic Reviews (CDSR)
http://www.cochrane.org/reviews/clibintro.htm

The online Cochrane Library was searched. The strategy used a combination of MeSH subject headings and text searches. The search is focused on ‘population’ and ‘interventions’. The search located 49 systematic reviews.

#1 MeSH descriptor Maternal Nutrition, this term only in MeSH products
#2 MeSH descriptor Postpartum Period, this term only in MeSH products
#3 MeSH descriptor Postnatal Care, this term only in MeSH products
MeSH descriptor Mothers, this term only in MeSH products
MeSH descriptor Single Parent, this term only in MeSH products
MeSH descriptor Surrogate Mothers, this term only in MeSH products
MeSH descriptor Single-Parent Family, this term only in MeSH products
mother* in Title, Abstract or Keywords in all products
maternal or postnatal or "post-natal" or " post natal" or postpartum or "post-partum" or "post partum" in Title, Abstract or Keywords in all products
MeSH descriptor Dietary Supplements, this term only in MeSH products
MeSH descriptor Health Education, this term only in MeSH products
MeSH descriptor Health Food, this term only in MeSH products
diet or dietary or nutrition or "vitamin b6" or "vitamin d" or "folic acid" or food supplement* or nutrient supplement* or healthy food* or "healthy eating" or "iron status" or "lactation performance" in Title, Abstract or Keywords in all products
(diet* or eating) near (advice or promot* or intake or counsel* or educat* or intervention* or supplement* or structured or habit* or attitude*) in Title, Abstract or Keywords in all products
(nutrition* or nutrient*) near (educat* or knowledge or intervention*) in Title, Abstract or Keywords in all products
MeSH descriptor Nutritional Requirements, this term only in MeSH products
MeSH descriptor Food explode all trees in MeSH products
MeSH descriptor Folic Acid, this term only in MeSH products
MeSH descriptor Diet, this term only in MeSH products
MeSH descriptor Zinc, this term only with qualifier: BL in MeSH products
MeSH descriptor Choline Deficiency, this term only in MeSH products
MeSH descriptor Lactation, this term only in MeSH products
MeSH descriptor Anemia, Iron-Deficiency, this term only in MeSH products
MeSH descriptor Iron, this term only with qualifier: DF in MeSH products
MeSH descriptor Nutrition, this term only in MeSH products
MeSH descriptor Nutrition Policy, this term only in MeSH products
MeSH descriptor Food Habits, this term only in MeSH products
MeSH descriptor Africa explode all trees in MeSH products
MeSH descriptor Caribbean Region explode all trees in MeSH products
MeSH descriptor Central America explode all trees in MeSH products
MeSH descriptor Latin America explode all trees in MeSH products
MeSH descriptor South America explode all trees in MeSH products
MeSH descriptor Asia explode all trees in MeSH products
MeSH descriptor Developing Countries, this term only in MeSH products
MeSH descriptor Food explode all trees in MeSH products
MeSH descriptor Lipids, this term only in MeSH products
MeSH descriptor Food Labeling, this term only in MeSH products
MeSH descriptor Feeding Behavior, this term only in MeSH products
MeSH descriptor Energy Intake, this term only in MeSH products
MeSH descriptor Communication, this term only in MeSH products
MeSH descriptor Health Education, this term only in MeSH products
MeSH descriptor Patient Education, this term only in MeSH products
MeSH descriptor Health Promotion, this term only in MeSH products
MeSH descriptor Health Knowledge, Attitudes, Practice, this term only in MeSH products
(#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
(#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44)
(#45 AND #46)
(#1 OR #47)
(#28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)
2. Database of Abstracts of Reviews of Effects (DARE) & Health Technology Assessment Database (HTA)

This search used the CRD DARE admin database (Cairs B), which contains DARE records and CDSR abstracts, and the CRD HTA admin database. The search is focused on ‘population’ and ‘interventions’. The search located 93 reviews in DARE and 14 in HTA.

1. S maternal(w5)nutrition
2. S postpartum
3. S post(w)partum
4. S postnatal
5. S post(w)natal
6. S (mother$ or matern$) or (single(w)parent$) or (surrogate(w)mother$)
7. S (food$ or diet$ or eating or nutrition or vitamin$ or (folic(w)acid) or nutrient$ or supplement$ or (healthy(w)eating) or (iron(w)status) or (lactation(w)performance) or zinc or (choline(w)deficiency) or (iron(w)deficiency) or lipids)
8. S (diet$ or eating or nutrition$ or nutrient or health)(w)(advice or promot$ or intake or requirements or counsel$ or educat$ or intervention$ or knowledge or supplement$ or structured or habit$ or attitude$)
9. S (food(w)labeling) or (feeding(w)behavior) or (energy(w)intake)
10. S communication
11. s s2 or s3 or s4 or s5 or s6
12. s s7 or s8 or s9 or s10
13. s s11 and s12
14. s s1 or s13
15. s@1995:2006
16. s s14 and s15

3. National Guideline Clearinghouse
   http://www.guideline.gov/
   Searched 01/02/06
   (mother* or postpartum or "matern*") and ("diet* or nutrition or "food*")
   231 results screened by hand. 2 relevant results added to Endnote library.

4. National Coordinating Centre for Health Technology Assessment (NCCHTA)
   http://www.hta.nhsweb.nhs.uk/
   Searched 01/02/06
   "nutrition"
   4 results- none relevant.

5. NICE WEBSITE
   http://www.nice.org.uk/page.aspx?o=home
   Searched 02/02/06
   nutrition
   2 results- 1 relevant added to Endnote library.
B) Searches for RCTs

Medline (Ovid, 1966 to Feb week 1 2006)

1 Maternal Nutrition/ (218)
2 postpartum period/ or postnatal care/ or (mother or mothers or maternal or postnatal or post-natal or (post adj natal) or postpartum or post-partum or (post adj partum)).ti,ab. (216030)
3 mothers/ or single parent/ or surrogate mothers/ or single-parent family/ (14873)
4 dietary supplements/ or health education/ or health food/ (48095)
5 (diet or dietary or nutrition or (vitamin adj d) or (vitamin adj b6) or (folic adj acid) or food supplement$ or nutrient supplement$ or healthy food$ or healthy eating or iron status or (lactat$ adj performance)).ti,ab. (244451)
6 ((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (23134)
7 ((nutrition$ or nutrient$) adj (educat$ or knowledge or intervention$)).ti,ab. (3466)
8 nutritional requirements/ or exp food/ or folic acid/ or exp diet/ or zinc/bl or choline deficiency/ or lactation/ or anemia, iron-deficiency/ or iron/df (531663)
9 nutrition/ or nutrition policy/ or food habits/ (36588)
10 exp africa/ or exp caribbean region/ or exp central america/ or exp latin america/ or exp south america/ or exp asia/ (430041)
11 DEVELOPING COUNTRIES/ (45153)
12 clinical trial.pt. or randomized.ab. or placebo.ab. or clinical trials/ or randomly.ab. or trial.ti. (590556)
13 fruit/ or vegetables/ (17682)
14 exp vitamins/ (167919)
15 lipids/ (59682)
16 food labeling/ or feeding behavior/ or energy intake/ (41781)
17 communication/ or health education/ or "health knowledge,attitudes,practice"/ or patient education/ or health promotion/ (158675)
18 or/2-3 (221343)
19 or/4-9,13-17 (992966)
20 18 and 19 (31539)
21 1 or 20 (31608)
22 or/10-11 (446555)
23 21 not 22 (27536)
24 23 and 12 (2062)
25 limit 24 to (humans and english language and yr="1990-2006") (1204)

1204 records were retrieved. 1172 records remained after deduplication.

Central (Cochrane Library 2006/1)

#1 MeSH descriptor maternal nutrition this term only 9
#2 MeSH descriptor postpartum period explode all trees 601
#3 MeSH descriptor postnatal care explode all trees 155
#4 ( (mother in Record Title or (mothers in Record Title and of in Record Title and maternal in Record Title) or postnatal in Record Title) or (mother in Tables or (mothers in Tables and of in Tables and maternal in Tables) or postnatal in Tables) ) from 1990 to 2006 799
#5 ( (post-natal in Record Title or "post natal" in Record Title or postpartum in Record Title or "post partum" in Record Title) or (post-natal in Abstract or "post natal" in Abstract or postpartum in Abstract or "post partum" in Abstract) ) from 1990 to 2006 1229
#6 MeSH descriptor mothers explode all trees 397
#7 MeSH descriptor Single-Parent Family explode all trees 2
#8 MeSH descriptor dietary supplements explode all trees 1942
#9 MeSH descriptor health education explode all trees 4561
#10 MeSH descriptor health food explode all trees 10
#11 ( (diet in Record Title or dietary in Record Title or nutrition in Record Title or "vitamin d" in Record Title or "vitamin b6" in Record Title) or (diet in Abstract or dietary in Abstract or nutrition in Abstract or "vitamin d" in Abstract or "vitamin b6" in Abstract) ) from 1990 to 2006 19652
#12 ( ("folic acid" in Record Title or "food supplement*" in Record Title or "nutrient supplement*" in Record Title) or ("folic acid" in Abstract or "food supplement*" in Abstract or "nutrient supplement*" in Abstract) ) 833
#13 ( ("healthy food" in Record Title or "healthy eating" in Record Title or "iron status" in Record Title or lactat* in Record Title) or ("healthy food" in Abstract or "healthy eating" in Abstract or "iron status" in Abstract or lactat* in Abstract) ) from 1990 to 2006 2889
#14 ( (diet* in Record Title or eating in Record Title or nutrition* in Record Title or nutrient* in Record Title) or (diet* in Abstract or eating in Abstract or nutrition* in Abstract or nutrient* in Abstract) ) from 1990 to 2006 16104
#15 MeSH descriptor nutritional requirements explode all trees 287
#16 MeSH descriptor food explode all trees 9388
#17 MeSH descriptor folic acid explode all trees 1230
#18 MeSH descriptor diet explode all trees 4876
766 records were retrieved. 324 records remained after deduplication.

Cinahl (Ovid interface, 1982 to February Week 1 2006)

1 maternal-child health/ (812)
2 exp postnatal period/ (2158)
3 exp mothers/ (6946)
4 (mother or mothers or maternal or postnatal or post-natal or post partum).ti,ab. (19500)
5 or/1-4 (23473)
6 exp health promotion/ or exp dietary supplements/ (11696)
7 exp health education/ or exp eating behavior/ (41867)
8 exp diet/ or exp nutritional requirements/ (15773)
9 exp food/ or folic acid/ or zinc/ or avitaminosis/ (21289)
10 exp lactation disorders/ or anemia/ (1392)
11 anemia, iron deficiency/ (627)
12 iron/ (965)
13 nutrition/ or exp nutrition policy/ or exp vitamins/ (12105)
14 exp lipids/ or food labeling/ or health knowledge/ (19034)
15 (diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$ or nutrient supplement$ or healthy food$ or health eating or iron status or lactat$ performance).ti,ab. (25713)
339 records were retrieved. 155 records remained after deduplication.

Embase (Ovid interface 1980 to 2006 week 06)

1 maternal nutrition/ (1995)
2 puerperium/ (7676)
3 mother/ or lactation/ (17349)
4 (mother or mothers or maternal or postnatal or post-natal or post natal or postpartum or post-partum or post partum).ti,ab. (163825)
5 or/2-3 (24210)
6 exp health education/ or diet supplementation/ (76840)
7 nutritional support/ or vitamin supplementation/ (10477)
8 folic acid/ or zinc/ or lactation disorder/ (46694)
9 iron deficiency anemia/ (4217)
10 exp nutrition/ or exp nutritional deficiency/ or exp vitamin deficiency/ (689391)
11 exp lipid/ (434920)
12 (diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$).ti,ab. (184221)
13 (nutrient supplement$ or healthy food$ or health eating or iron status or lactact$ performance).ti,ab. (2294)
14 ((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (20758)
15 nutrient supplement$.ti,ab. (278)
16 ((nutrition$ or nutrient$) adj (educat$ or knowledge or intervention$)).ti,ab. (2588)
17 or/6-16 (1117771)
18 5 and 17 (8216)
19 1 or 18 (9876)
20 limit 19 to (human and english language) (6629)
21 limit 20 to yr="1990 - 2006" (5671)
22 exp africa/ or exp "south and central america"/ or developing country/ or exp asia/ (210412)
23 21 not 22 (4710)  
24 controlled study/ or exp clinical trial/ or outcomes research/ or randomized controlled trial/ (2323666)  
25 (randomized or placebo or randomly).ab. or trial.ti. (275185)  
26 or/24-25 (2413063)  
27 23 and 26 (2071)  

2071 records retrieved. 1435 records remained after deduplication.

PsycINFO (Ovid interface 1985 to January Week 5 2006)

1 exp mothers/ or postnatal period/ or lactation/ or single mothers/ or unwed mothers/ (17852)  
2 (mother or mothers or maternal or postnatal or post-natal or post natal or postpartum or post-partum or post partum).ti,ab. (52280)  
3 or/1-2 (54328)  
4 exp nutrition/ (2236)  
5 health promotion/ or health attitudes/ or health education/ or health knowledge/ (14454)  
6 exp food/ (2498)  
7 food intake/ or eating habits/ or eating patterns/ (6110)  
8 exp dietary supplements/ or exp nutritional deficiencies/ (1447)  
9 folic acid/ or zinc/ or exp vitamins/ (1448)  
10 anemia/ or exp lipids/ (2042)  
11 (diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$ or nutrient supplement$ or healthy food$ or healthy eating or iron status or lactat$ performance).ti,ab. (10845)  
12 ((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (2438)  
13 ((nutrition$ or nutrient$) adj (educat$ or knowledge or intervent$ or supplementation$ or structured or habit$ or attitude$)).ti,ab. (423)  
14 or/4-13 (35133)  
15 3 and 14 (1775)  
16 developing countries/ or africa.lo. (5188)  
17 15 not 16 (1732)  
18 limit 17 to (human and english language and yr="1990 - 2006") (1043)  
19 (empirical study or quantitative study).md. (805985)  
20 treatment outcome clinical trial.md. or experimental design/ (14120)  
21 (randomized or placebo or randomly).ab. or trial.ti. (40818)  
22 or/19-21 (814937)  
23 18 and 22 (887)  

887 records retrieved. 736 records remained after deduplication.

C) Searches for UK studies (Non-RCTs, non-reviews)

Medline  (Ovid interface, 1966 to February Week 1 2006)

1 Maternal Nutrition/ (218)  
2 postpartum period/ or postnatal care/ or (mother or mothers or maternal or postnatal or post-natal or postnatal or post partum or post-partum or post partum).ti,ab. (216030)  
3 mothers/ or single parent/ or surrogate mothers/ or single-parent family/ (14873)  
4 dietary supplements/ or health education/ or health food/ (48095)
Cinahl (Ovid interface, 1982 to February Week 1 2006)

1 maternal-child health/ (812)
2 exp postnatal period/ (2158)
3 exp mothers/ (6946)
4 (mother or mothers or maternal or postnatal or post-natal or post natal or postpartum or post-partum or post partum).ti,ab. (19500)
5 or/1-4 (23473)
6 exp health promotion/ or exp dietary supplements/ (11696)
7 exp health education/ or exp eating behavior/ (41867)
8 exp diet/ or exp nutritional requirements/ (15773)
9 exp food/ or folic acid/ or zinc/ or avitaminosis/ (21289)

680 records were retrieved. 619 records remained after deduplication.
10 exp lactation disorders/ or anemia/ (1392)
11 anemia, iron deficiency/ (627)
12 iron/ (965)
13 nutrition/ or exp nutrition policy/ or exp vitamins/ (12105)
14 exp lipids/ or food labeling/ or health knowledge/ (19034)
15 (diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$ or nutrient supplement$ or healthy food$ or health eating or iron status or lactat$ performance).ti,ab. (25713)
16 ((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (3115)
17 ((nutrition$ or nutrient$) adj (educat$ or knowledge or intervention$)).ti,ab. (1329)
18 or/6-17 (104755)
19 5 and 18 (4023)
20 exp africa/ or exp west indies/ or exp central america/ or latin america/ or exp south america/ (15285)
21 exp asia/ or developing countries/ (24200)
22 or/20-21 (38584)
23 19 not 22 (3418)
24 exp clinical trials/ (35215)
25 double-blind studies/ (7038)
26 single-blind studies/ (1840)
27 triple-blind studies/ (31)
28 clinical trial.pt. (16256)
29 random assignment/ (11877)
30 (randomized or placebo or randomly).ab. or trial.ti. (29078)
31 or/24-30 (51694)
32 23 and 31 (348)
33 limit 32 to (english and yr="1990 - 2006") (339)
34 from 33 keep 1-10 (10)
35 exp united kingdom/ (91416)
36 (united kingdom or uk or wales or scotland or england or ireland or great britain).in. (43597)
37 or/35-36 (120387)
38 23 and 37 (357)
39 (review or systematic review).pt. (49101)
40 38 not (31 or 39) (298)
41 limit 40 to (english and yr="1990 - 2006") (292)

292 records were retrieved. 229 records remained after deduplication.

Embase (Ovid interface, 1980 to 2006 Week 06)

1 maternal nutrition/ (1995)
2 puerperium/ (7676)
3 mother/ or lactation/ (17349)
4 (mother or mothers or maternal or postnatal or post-natal or post natal or postpartum or post-partum or post partum).ti,ab. (163825)
5 or/2-3 (24210)
6 exp health education/ or diet supplementation/ (76840)
7 nutritional support/ or vitamin supplementation/ (10477)
8 folic acid/ or zinc/ or lactation disorder/ (46694)
9 iron deficiency anemia/ (4217)
10 exp nutrition/ or exp nutritional deficiency/ or exp vitamin deficiency/ (689391)
11 exp lipid/ (434920)
(diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$).ti,ab. (184221)
(nutreint supplement$ or healthy food$ or health eating or iron status or lactact$ performance).ti,ab. (2294)
((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (20758)
nutrient supplement$.ti,ab. (278)
((nutrition$ or nutrient$) adj (educat$ or knowledge or intervention$)).ti,ab. (2588)
or/6-16 (1117771)
5 and 17 (8216)
1 or 18 (9876)
limit 19 to (human and english language) (6629)
limit 20 to yr="1990 - 2006" (5671)
exp africa/ or exp "south and central america"/ or developing country/ or exp asia/ (210412)
21 not 22 (4710)
controlled study/ or exp clinical trial/ or outcomes research/ or randomized controlled trial/ (2323666)
(randomized or placebo or randomly).ab. or trial.ti. (275185)
or/24-25 (2413063)
23 and 26 (2071)
from 27 keep 1-2071 (2071)
united kingdom/ (67221)
(united kingdom or uk or wales or scotland or england or ireland or great britain).in. (835857)
review.pt. (630324)
meta analysis/ or systematic review/ (28818)
or/29-30 (853938)
or/31-32 (646156)
23 and 33 (605)
35 not (26 or 34) (254)

254 records were retrieved. 210 records remained after deduplication.

PsycINFO (Ovid interface, 1985 to January Week 5 2006)

1  exp mothers/ or postnatal period/ or lactation/ or single mothers/ or unwed mothers/ (17852)
2  (mother or mothers or maternal or postnatal or post-natal or post natal or postpartum or post-partum or post partum).ti,ab. (52280)
3  or/1-2 (54328)
4  exp nutrition/ (2236)
5  health promotion/ or health attitudes/ or health education/ or health knowledge/ (14454)
6  exp food/ (2498)
7  food intake/ or eating habits/ or eating patterns/ (6110)
8  exp dietary supplements/ or exp nutritional deficiencies/ (1447)
9  folic acid/ or zinc/ or exp vitamins/ (1448)
10  anemia/ or exp lipids/ (2042)
11  (diet or dietary or nutrition or vitamin d or vitamin b6 or folic acid or food supplement$ or nutrient supplement$ or healthy food$ or healthy eating or iron status or lactact$ performance).ti,ab. (10845)
12  ((diet$ or eating) adj (advice or promot$ or intake or counsel$ or educat$ or intervention$ or supplement$ or structured or habit$ or attitude$)).ti,ab. (2438)
The searches for three reviews conducted in early 2006 were updated:

- Nutrition of postpartum mothers
- Nutrition of babies 0-6 months
- Nutrition of children aged 7 months to 5 years

Where possible the original saved searches were rerun. Where saved searches were not available the original search strategies as recorded in the original search writeup were retyped into the relevant database/search engines.

A total of 681 additional citations were identified (19 systematic reviews, 526 randomised controlled trials and 136 UK studies).
APPENDIX D – Methodology checklist


Notes on the use of methodology checklist: randomised controlled trials

Section 1 identifies the study and asks a series of questions aimed at establishing the internal validity of the study under review – that is, making sure that it has been carried out carefully, and that the outcomes are likely to be attributable to the intervention being investigated. Each question covers an aspect of methodology that research has shown makes a significant difference to the conclusions of a study. For each question in this section you should use one of the following to indicate how well it has been addressed in the study.

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (that is, not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (that is, mentioned, but insufficient detail to allow assessment to be made)
- Not applicable

The study addresses an appropriate and clearly focused question.

Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

The assignment of subjects to treatment groups is randomised.

Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study. If there is no indication of randomisation, the study should be rejected. If the description of randomisation is poor, or the process used is not truly random (for example, allocation by date, alternating between one group and another) or can otherwise be seen as flawed, the study must be given a lower quality rating.

An adequate concealment method is used.

Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%. Centralised allocation, computerised allocation systems or the use of coded identical containers would all be regarded as adequate methods of concealment, and may be taken as indicators of a well-conducted study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating, and can be rejected if the concealment method is seen as inadequate. B.2.4 Subjects and investigators are kept ‘blind’ about treatment allocation. Blinding can be carried out up to three levels. In single-blind studies, patients are unaware of which treatment they are receiving; in double-blind studies the doctor and the patient are unaware of which treatment the patient is receiving; in triple-blind studies patients, healthcare providers and those conducting the analysis are unaware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.
The treatment and control groups are similar at the start of the trial. Patients selected for inclusion in a trial should be as similar as possible, in order to eliminate any possible bias. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin or comorbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

The only difference between groups is the treatment under investigation. If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution, and given a low quality rating.

All relevant outcomes measured in a standard, valid and reliable way. If some significant clinical outcomes have been ignored, or not adequately taken into account, the study should be downgraded. It should also be downgraded if the measures used are regarded as being doubtful in any way, or applied inconsistently.

What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop-out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop-out rate may be expected to be higher in studies conducted over a long period of time. A higher drop-out rate will normally lead to downgrading, rather than rejection of a study.

All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention-to-treat analysis). In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated, irrespective of the treatment they actually received. (This is known as intention-to-treat analysis.) If it is clear that the analysis was not on an intention-to-treat basis, the quality of the study should be downgraded.

Where the study is carried out at more then one site, results are comparable for all sites. In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.
Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

| ++ | All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter. |
| +  | Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions. |
| –  | Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter. |

The code allocated here, coupled with the study type, will decide the level of evidence that this study provides. The aim of the other two questions in this section is to summarise your view of the quality of this study and its applicability to the patient group targeted by the guideline you are working on.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process.
Methodology checklist for RCTs included in Nutrition for Postnatal Mothers Rapid Review

First author/year

Article I. Section 1: internal validity

<table>
<thead>
<tr>
<th></th>
<th>In a well-conducted RCT study:</th>
<th>In this study this criterion is: (copy one option into your column with comment if required)</th>
<th>Reviewer 1 (initials)</th>
<th>Reviewer 2 (initials)</th>
<th>Direction =, +, -</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept 'blind' about treatment allocation</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Coveredness</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Not reported Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation</td>
<td>Not reported Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid way</td>
<td>Not reported Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Number randomised into each arm Number in each arm with outcome data at the end of the trial Dropout rate (%) for each arm Dropout rate (%) overall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention-to-treat)</td>
<td>Not reported Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>as intention to treat analysis, ITT)</td>
<td>Not reported</td>
<td>Not applicable</td>
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<td></td>
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<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Poorly addressed</td>
<td>Not addressed</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Not reported</td>
<td>Not applicable</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Article II. Section 2: Overall assessment of the study

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Reviewer 1</th>
<th>Reviewer 2</th>
<th>(Reviewer 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>Code ++, + or -</td>
<td>(initials)</td>
<td>(initials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Comment if desired</td>
<td>Comment if desired</td>
</tr>
<tr>
<td>2.2</td>
<td>If coded as + or – what is the likely direction in which bias might affect the study results?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain the overall effect is due to the study intervention?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

72