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Food-support programmes for low-income and socially disadvantaged childbearing women in developed countries

Systematic review of the evidence

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Foreword

The Health Development Agency (HDA) was established in 2000. Between then and 2005, when the functions of the HDA were transferred to the National Institute for Health and Clinical Excellence (NICE), the HDA helped to build the evidence base in public health with an emphasis on what works and a special focus on reducing inequalities in health.

The HDA had the task of mapping and synthesising the evidence across priority areas of public health. It developed a number of ways of taking a systematic approach to compiling the evidence, identifying gaps and making the evidence base accessible. The evidence briefing series was one of the ways in which the HDA Evidence Base was disseminated (full details of the process of developing the Evidence Base and the associated methodological activities can be found in Graham and Kelly 2004; Kelly et al. 2002, 2003, 2004; Killoran and Kelly 2004; Swann et al. 2005).

The necessity for reviewing reviews, or tertiary-level research, stems from the proliferation over the last decade, or more, of systematic and other types of review in medicine and public health. The HDA published a range of evidence briefings that cover:

- Teenage pregnancy and parenthood
- HIV prevention
- Prevention of sexually transmitted infections
- Management of obesity and overweight
- Ante- and post-natal home-visiting programmes
- Prevention of low birth weight
- Breastfeeding
- Accidental injuries in children and older people
- Public health interventions for increasing physical activity among adults
- Smoking and public health
- Drug misuse
- Youth suicide prevention
- Health impact assessment
- Prevention and reduction of alcohol misuse
- Prevention and reduction of exposure to second-hand smoke
- Secondary interventions for chronic illness
- Housing.

Taken together these briefings provide a comprehensive synthesis of the evidence drawn from review-level literature. They are available on the NICE website – www.publichealth.nice.org.uk

These evidence briefings have been based on evidence drawn from systematic and other kinds of reviews. This means that the type of evidence that does not traditionally find its way into reviews has not been considered in detail for these documents.

To address this evidence gap, in another HDA evidence series, evidence reviews, of which this is one, the scope of the coverage is extended to primary research, other kinds of evidence and other types of study. Evidence reviews are traditional reviews, overviews or syntheses of multiple evidence sources drawn from different research traditions. These take a variety of forms and formats (see for example the evidence reviews on drug misuse prevention (Coomber et al. 2004a) and risky behaviour (Coomber et al. 2004b). In some cases evidence reviews consist of analyses of primary studies, drawn from the published and unpublished literature. In other cases they comprise summaries of the theoretical concepts and ideas that relate to the evidence base in public health. Overall, evidence reviews provide a general evidence resource on a range of public health topics.

The construction of the HDA Evidence Base involved collaboration with a number of partners who have interests and expertise in practical and methodological matters concerning the drawing together of evidence and its dissemination. In particular the HDA acknowledged the following: the Centre for Reviews and Dissemination at the University of York; the EPPI-Centre at the Institute of Education at the University of London; Health Evidence Bulletins Wales; the ESRC UK Centre for Evidence Based Policy and Practice at Queen Mary College, University of London and its nodes at the City University London and the MRC Public Health Sciences Unit at the University of Glasgow; members of the Cochrane and Campbell collaborations; the United Kingdom and Ireland Public Health Evidence Group and the members of the Public Health Evidence Steering Group. This latter organisation acted as the overall guide for the HDA's evidence-building project. The cooperation of colleagues in these institutions and organisations has been of significant help in the general work in preparing the framework for how we assess the evidence.

Every effort has been made to be as accurate and up-to-date as possible in the preparation of this evidence review. However, we would be very pleased to hear from readers who would like to comment on the content or on any matters relating to the accuracy of the review. We will make every effort to correct any matters of fact in subsequent editions.

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Contents

Summary

Poverty predisposes childbearing women and their babies to poor nutritional and health outcomes (Institute of Medicine 1996), and to health behaviours such as smoking that worsen the negative impact of poverty on birth outcomes (Hamlyn et al. 2002; Penn and Owen 2002). Babies born to low-income women are at higher risk of low birth weight. Low birth weight babies are more likely to suffer serious morbidities during the first year of life and are more likely to die before their first birthday (Macfarlane and Mugford 2000). This disadvantage appears to follow them into adult life with greater odds of developing hypertension and diabetes (Barker 1992), and dying earlier than those born with birth weights within the normal range (Syddall et al. 2005).

Childbearing women living on low incomes have difficulty in accessing healthy diets (Rogers and Emmet 1998). The Avon Longitudinal Study of Pregnancy and Childhood (ALSPAC) found that only three nutrients among the 20 studied in the diets of women were unaffected by financial constraints (Rogers and Emmet 1998). Pregnant teenagers, the large proportion of whom live on very low incomes, have unhealthy diets and often skip meals because of lack of money (Burchett 2003). Women from marginalised minority ethnic groups have diets deficient in a number of key nutrients (Rees et al. 2005). However, the link between maternal diet and fetal and child health in industrialised countries is as yet unclear (Enkin et al. 2000).

Notwithstanding the lack of evidence linking maternal diet to perinatal outcomes, public health programmes provide food supplements and nutritional advice to childbearing women in the expectation that they will bring about improvements in the health not only of mothers but of their babies as well. Well-known programmes in developed countries are the Special Supplemental Nutrition Programme for Women, Infants and Children (WIC) in the USA, and the Welfare Food Scheme in the UK. Expected outcomes of such programmes include:

- improvements in maternal nutrient intake, haematological and biochemical indices and uptake of maternity services
- increase in maternal weight gain
- reduction in rates of low birth weight, intrauterine growth retardation, pre-term birth and perinatal mortality
- increases in mean birth weight and duration of gestation
- reduction in rates of health-related behaviours such as maternal smoking
- improvements in other physical and psychological health outcomes in the first year of life
- increases in breastfeeding initiation and duration.

These outcomes are expected for a woman's first pregnancy. Existing national food-support programmes such as WIC do not aim to change long-term outcomes such as perinatal outcomes in subsequent pregnancies. The Welfare Food Scheme is scheduled to be replaced by a new scheme, Healthy Start, in 2006/7.

The health status and financial condition of mothers and their babies came into focus after the release of the report, *Independent inquiry into inequalities in health* (Acheson 1998), and was addressed in a series of policy initiatives including a programme to tackle inequalities in infant mortality and life expectancy at birth (Department of Health (1999b, 2000, 2003). The public health white paper, *Choosing Health* (Department of Health 2004), continued the policy commitment to address health inequalities, giving high priority to tackling smoking, and supporting maternal and child nutrition in low-income groups through the new Healthy Start scheme.

This review studies the effectiveness and cost effectiveness of food-support programmes that aim to have an impact on low birth weight and other outcomes related to maternal and infant nutrition. It was commissioned by the Health Development Agency (HDA) as part of the work of the Public Health Collaborating Centre for Maternal and Child Nutrition and is published by the National Centre for Health and Clinical Excellence (NICE) as a result the HDA's functions being transferred to NICE in 2005.

Methodology

- A review of the literature was carried out in accordance with systematic review methodology.
- Studies of childbearing women in developed countries who were in low-income or in otherwise disadvantaged groups were included.
- Interventions of interest were those that aimed to improve maternal nutritional intake.
- The primary outcome of interest is low birth weight.
- Other indicators used as proxies for low birth weight were mean birth weight, gestational age at birth, intrauterine growth retardation, perinatal and infant mortality, maternal weight change and maternal nutritional status.
- A search strategy was developed on the basis of the inclusion criteria, and 15 electronic databases were searched.
- Studies were appraised for quality only after inclusion in the review.

Results

The search resulted in approximately 9500 citations. A total of 348 papers were retrieved, of which 19 intervention studies met all the inclusion criteria, while 12 cost-analysis studies met the inclusion criteria for the economic section of this review. Of the 19 intervention papers, six studies of WIC were included, two of which were large-scale national evaluations. The others were three studies of stand-alone nutrition supplements, eight of nutritional advice/education/counselling, and two complex healthcare interventions that had a nutrition component.

With respect to the primary outcome of interest, low birth weight, the results of this review do not provide evidence that food-support programmes have any impact. However, there are favourable impacts on other outcomes. There is indicative evidence* of an increase in mean birth weight of babies born to heavy smokers, a high proportion of whom are in low-income groups. There is also evidence of the beneficial impact of food support on maternal weight gain and dietary intake in a woman's first pregnancy.

The economic studies included in this review do not provide reliable evidence of the cost effectiveness of food-support programmes.

The key findings of the review follow (CT = controlled trial; RCT = randomised controlled trial).

Effectiveness of WIC

- Prenatal WIC participation is likely to result in increased maternal weight gain; this effect is enhanced when participation begins earlier in pregnancy and lasts longer *(moderately strong evidence from one CT)*
- Prenatal WIC participation is likely to result in increased intakes of energy, protein, vitamin B6, iron, thiamin, riboflavin, vitamin C and calcium *(moderately strong evidence from one CT)*
- Prenatal WIC participation is likely to result in higher energy intake among heavy smokers *(moderately strong evidence from one CT)*
- Postpartum WIC participation is likely to result in increased haemoglobin concentration and reduced rates of anaemia among non-lactating women, if participation is uninterrupted for 6 months *(moderately strong evidence from one CT)*
- Prenatal WIC participation is likely to result in increased newborn head circumference *(moderately strong evidence from one CT)*
- Prenatal WIC participation is likely to result in reduced rates of premature rupture of membranes *(moderately strong evidence from one CT)*
- Prenatal WIC participation is likely to result in more women receiving nutrition counselling sessions and more receiving more than two sessions *(moderately strong evidence from one CT)*
- Mean birth weight of babies born to smokers, particularly heavy smokers, probably improves as a result of prenatal WIC participation (*moderately strong evidence from one RCT)*

* Indicative evidence – findings from the included studies that are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

- Higher programme quality may improve perinatal outcomes *(moderately strong evidence from one CT)*
- Prenatal WIC participation is unlikely to reduce rates of low birth weight *(moderately strong evidence from one RCT and one CT)*
- Prenatal WIC participation is unlikely to raise mean birth weight in the whole population, ie smokers and non-smokers *(moderately strong evidence from one RCT and one CT)*
- Prenatal WIC participation is unlikely to reduce rates of pre-term birth or increase duration of gestation *(moderately strong evidence from one RCT and one CT)*
- Prenatal WIC participation is unlikely to increase the uptake of prenatal care *(moderately strong evidence from one CT)*
- Prenatal WIC participation probably does not result in increased maternal haemoglobin concentration at 36 weeks gestation *(moderately strong evidence from one CT)*
- Prenatal WIC participation probably does not have an effect on reduction in the time women work outside the home during their pregnancy *(moderately strong evidence from one CT)*
- There is insufficient evidence of the effect of prenatal WIC participation on fetal survival.

Effectiveness of stand-alone high-protein and protein-energy supplements

- Stand-alone high-protein supplements are very likely to result in early pre-term births among women who had adequate protein intake at baseline *(strong evidence from one RCT)*
- Stand-alone high-protein supplements are very likely to result in intrauterine growth retardation among women who had adequate protein intake at baseline *(strong evidence from one RCT)*
- Stand-alone balanced protein-energy and high-protein supplements are very unlikely to result in increased mean birth weight among all study participants (smokers + non-smokers) *(strong evidence from one RCT)*
- Stand-alone balanced protein-energy supplements are very likely to result in an increase in length of gestation *(strong evidence from one RCT)*
- Stand-alone balanced protein-energy and high-protein supplements are likely to result in an increase in mean birth weight of babies born to heavy smokers *(strong evidence from one RCT)*
- Stand-alone high-protein supplements are likely to result in improvement in some infant psychological outcomes at 1 year *(strong evidence from one RCT)*
- Stand-alone protein-energy supplements are unlikely to improve somatic outcomes in infants *(strong evidence from one RCT)*

Effectiveness of nutrition education and/or counselling

- Nutrition education interventions aimed at improving poor diets are likely to improve intakes of calcium, protein, carbohydrate, vitamin C, niacin, riboflavin and thiamin but not iron or fat intake *(moderately strong evidence from one RCT and one CT)*
- Nutrition education interventions aimed at improving poor diets are likely to reduce the proportion of women with low levels of calcium, ascorbic acid and riboflavin *(moderately strong evidence from one RCT)*
- Nutrition education aimed at reducing the risk of gestational diabetes in a high-risk group is likely to result in improvements in folic acid intake at 6 months postpartum *(moderately strong evidence from one before-after study)*
- Nutrition counselling may have an impact on mean birth weight *(moderately strong evidence from one CT)*
- Nutrition education targeting a high-risk group is unlikely to reduce their risk of developing gestational diabetes, reduce their maternal energy intake during pregnancy, or reduce mean birth weight of their babies *(moderately strong evidence from one before-after study)*
- Nutrition counselling probably has no impact on rates of low birth weight *(moderately strong evidence from two CTs and one before-after study)*
- Nutrition counselling probably has no impact on gestational age at birth, newborn head circumference or length at birth *(moderately strong evidence from two CTs and one before-after study)*

Effectiveness of complex health and social care interventions including a nutrition component

- Complex health and social care interventions are very likely to reduce rates of pre-term birth among heavy smokers (≥ 15 cigarettes/day) *(strong evidence from one RCT)*
- Complex health and social care interventions are very likely to reduce the number of cigarettes smoked each day *(strong evidence from one RCT)*

- Complex health and social care interventions are very unlikely to have a favourable impact on low birth weight and mean birth weight *(strong evidence from two RCTs)*
- Complex health and social care interventions are very unlikely to have a favourable impact on gestational age at birth *(strong evidence from one RCT)*
- Complex health and social care interventions are unlikely to have an impact on maternal weight gain *(strong evidence from one RCT)*
- Complex health and social care interventions may have a small impact on mean birth weight of babies born to very young mothers *(moderately strong evidence from one RCT)*

Conclusions

Historically, food-support programmes have aimed at improving key maternal and perinatal outcomes (Institute of Medicine 1996). The lack of any significant impact on low birth weight, pre-term birth and other perinatal outcomes along with the favourable impact on maternal weight gain and nutrient intakes provide a basis both for re-thinking the aims and objectives of current food-support programmes, and for searching for other means of improving perinatal outcomes. Setting out-of-reach goals for food-support programmes such as reduction in rates of low birth weight and pre-term birth is probably not useful until there is strong evidence of what works to improve those outcomes.

Childbearing women in the UK have diets that are known to be deficient in key nutrients (Rogers and Emmet 1998). Furthermore those living on low incomes face financial difficulties in feeding themselves and their children (Rogers et al. 1998). In this respect, teenage mothers are perhaps the most vulnerable group. Programmes providing women with food supplements are therefore likely to help them and their children to eat healthier diets. This in itself is a desirable outcome for any programme. In-depth studies of the diets of women from socially-disadvantaged groups would help to improve the efficiency of a food-support programme in a defined service area.

Women all over the world, particularly those in low-income groups, often complain of tiredness and exhaustion during pregnancy, postnatally and while breastfeeding. There has been little research into tiredness in pregnancy (Enkin et al. 2000). It is important for robust studies to be undertaken of the impact of food supplementation on these health outcomes and others such as postnatal depression. Improvements in maternal health outcomes will inevitably play a role in women's return to work.

Perhaps the most important gap in the evidence base is the lack of study of the long-term effects of food support on maternal and child health. Evaluations of interventions included in this review are limited to outcomes in the first pregnancy for both mother and baby; none of the included studies addressed outcomes in subsequent pregnancies. Experts in the field of maternal nutrition recommend a life-course approach to improving perinatal outcomes among women living on low incomes. Therefore, evaluations of food-support programmes need to study the impact of maternal nutrition supplementation on subsequent births and on the health of infants, children and adults born to women who received food supplements during pregnancy. The results of on-going studies are awaited (Tang et al. 2004).

Further research is required to find out more about deficiencies in the diets of childbearing women in the UK, and to study the impact of the new welfare food scheme, Healthy Start. A robust national evaluation of the new programme should be prospective in design with a priori sample size calculation for key outcomes. Such a study should follow women through subsequent pregnancies, and their children through into adult life. A qualitative component to such a study would ensure that women's views of the importance of nutrition, barriers to accessing healthy diets, and the content and delivery of the new programme are given due importance.

1 Introduction

Recognition of the need for healthier diets during pregnancy and the early years for low-income women and their babies has led to the introduction of food-support programmes in both developing and developed countries. In policy terms, food support is seen to have the potential to improve nutritional and health outcomes for people living in poverty. Well-known national programmes in developed countries are the Special Supplemental Nutrition Programme for Women, Infants and Children (WIC) and the Expanded Food and Nutrition Education Programme (EFNEP) in the USA; and the Welfare Food Scheme in the UK. A number of smaller programmes such as the Higgins nutrition intervention programme in Canada for particularly vulnerable childbearing women such as teenagers, are based on the same principles as the major national programmes.

The underlying premise of food-support programmes is that low income and/or reduction in food availability predisposes childbearing women and their children to poor nutritional status and consequently poor health outcomes (Institute of Medicine 1996). Changes in nutritional intake, one of the proximal determinants of maternal and infant nutritional status, and the one most amenable to intervention, can be achieved through health promotion interventions and provision of nutrition supplements. These approaches are central to most food-support programmes targeting women and children who are at nutritional risk.

1.1 Pregnancy outcome, socio-economic status and nutritional risk

Epidemiological reviews and analyses of routine data for England and Wales show that there is a direct link between birth weight and socio-economic status, with a higher incidence of low birth weight (< 2500g) among babies born into less privileged households (Botting 1997; Kramer 2003; Macfarlane and Mugford 2000). The proportion of low birth weight is higher among babies whose fathers are in manual occupations, among single mothers and in inner-city populations. Smoking in pregnancy, a health-related behaviour more common in low-income groups, further increases the risk of low birth weight. Preterm birth and impaired fetal growth are two leading causes of low birth weight. Impaired fetal growth has been linked to poor health outcomes in infancy and early childhood and an increased risk of heart disease, stroke and diabetes in adult life (Barker 1992).

There has been some debate about the link between maternal nutrition and fetal growth, but available evidence from UK studies is inconclusive. For example, Mathews et al. (1999) studied the relationship between birth weight and maternal nutritional status in a sample of 693 primigravid women in Portsmouth, who were not specifically from low-income groups. They found that placental weight and birth weight were unrelated to intake of any macro-nutrient. Early in pregnancy only vitamin C was found to be independently associated with birth weight. In their study of 538 Southampton mothers Godfrey et al. (1996) found that high intake of carbohydrate in early pregnancy and low intake of animal protein in late pregnancy was associated with lower birth weight. Approximately 20% of the sample was in social classes IV and V.

Evidence of a link between maternal dietary intake of women from industrialised nations and pregnancy outcomes is not strong. The only exception to date is folic acid intake – the evidence is indisputable that adequate folate intake in the periconceptional period is directly linked to a lower number of neural tube defects in the newborn (Murphy et al. 2000). Further to this there is a small but growing body of evidence linking single and multiple micro-nutrient deficiencies with other congenital defects (Keen et al. 2003).

An important question relevant to this review is whether there is evidence that women living on low-incomes and other socially disadvantaged women (who have a higher risk of low birth weight, growth retarded and pre-term babies) have poor diets. Mothers on state benefits may not be able to afford a healthy diet (Dallison and Lobstein 1995; Lobstein 1991) and may reduce their own intake to feed their children (Dobson et al. 1994; Dowler and Calvert 1995).

The Avon Longitudinal Study of Pregnancy and Childhood (ALSPAC) estimated the dietary intakes of 11,923 pregnant women in the South West of England (Rogers et al. 1998; Rogers and Emmet 1998). Mean intakes of energy, iron, folate, magnesium and potassium were lower than the reference nutrient intakes (RNI) for pregnant women for all study participants. Supplementary vitamin and mineral use during pregnancy were low and iron supplements were taken by less than a quarter (22.5%) of pregnant women before 18 weeks of pregnancy; this percentage nearly doubled by 32 weeks. The corresponding figures for folate supplements were 9% and 18%. There was a strong relationship between difficulty in affording food, and food and nutrient intake (Rogers et al. 1998).

Another study of non-pregnant women in Southampton aged 20–34 found that those who smoked, lived with children, had low educational achievement or did not take strenuous exercise were less likely to consume a 'prudent' diet (Inskip et al. 2004). Red cell folate levels were 10% higher in women with a degree than those without qualifications.

A number of studies have been conducted among childbearing women in east London in the last two decades; east London has a high rate of low birth weight compared with the rest of the city (Office for National Statistics 2000). These studies have revealed a high prevalence of poor nutrition during pregnancy (Doyle et al. 1989, 1990; Rees et al. 2002).

A recent study compared the nutrient intakes of 165 east London mothers from different ethnic groups who had given birth to low birth weight babies (Rees et al. 2005). This study, a re-analysis of baseline data collected for two earlier intervention studies, found a high prevalence of under-nutrition among mothers of low birth weight babies. Folate and iron intakes were lower than the RNI in all ethnic groups, while vitamin D intake was lower among Asian and Caucasian women compared with African women. Nearly 90% of women studied did not meet the RNI for iron.

In another local study of 89 low-income pregnant women in a Sure Start area in the North of England, energy intake was found to be less than the RNI but similar to ALSPAC participants (Ford 2004). Fibre intake among these women was much lower than both the RNI and that reported in the ALSPAC study. Iron and folate intakes were also low in this sample of pregnant women. Those living in the most deprived wards of the study area had higher calcium and sodium intakes and significantly lower intakes for most of the minerals studied.

The Southampton Women's Survey (SWS), currently underway, is said to include almost the whole range of Townsend deprivation scores and a wide range of social groups. It aims to characterise the diets of 3000 pregnant women for whom information is available from even before their pregnancies. Results from this survey are awaited (see the SWS site at the MRC Environmental Epidemiology Unit, www.mrc.soton.ac.uk).

Overall, the common findings from these studies point to low iron and folate intakes among childbearing women in the UK, with lower rates among poor women.

Overweight and obesity are more prevalent among low-income groups. A survey of women in England found that 28% of women in social class V were obese compared with half that number in social class I (Department of Health 1999a). Improved nutrition in pregnancy could play a part in reducing obesity and in establishing patterns of healthy eating for the woman and the family.

To complicate the question of the link between diet and low income, smoking, which is more common among groups of disadvantaged women, may be independently associated with nutrient intakes during pregnancy. Mathews et al. (1999) found a 104g decrease in birth weight among babies of smokers, and Godfrey et al. (1996) a decrease of 148g. Ethnic differences in fetal size can be attributed to maternal weight, height and other factors (Drooger et al. 2005) but the association between diet and ethnicity is not as clear.

1.2 Poor diets and financial constraints

Rogers et al. (1998) found that only three nutrients among the 20 studied in the ALSPAC sample were unaffected by financial constraints. Independent of smoking status, but not of age, poorer women had lower nutrient intakes. Findings from this study are similar to those suggested earlier by Wynn et al. (1994). In a recent study of the diets of pregnant teenagers, a large proportion of whom came from low-income groups, Maternity Alliance found that these young mothers often skip meals due to lack of money (Burchett 2003). They are more likely to eat cheap and unhealthy foods such as chips. Jayaweera and colleagues, in a small study of Bangladeshi women living in the UK, describe how low income and hardship impact on women's health and wellbeing during pregnancy and early motherhood (Jayaweera et al. 2005).

1.3 Existing public health policies

Ever since the report, *Independent inquiry into inequalities in health* (Acheson 1998), the health status and financial condition of mothers and their babies has come into focus. *Our Healthier Nation*, the government's white paper that followed, highlighted the need for policies and programmes targeting childbearing women and their children, with the specific aim of reducing inequalities in the health of the UK population (Department of Health 1999b). *The NHS Plan* defined targets to reduce inequalities, including a reduction by 10% in the rate of infant mortality between the highest and lowest income groups in the country (Department of Health 2000).

More recently, *Tackling Health Inequalities: a programme for action*, planned to tackle inequalities in infant mortality and life expectancy at birth (Department of Health 2003). Key strategies include improving nutrition in pregnancy and the early years; reducing smoking during pregnancy; improving the quality and accessibility of antenatal care and early years support; and supporting teenage parents. The public health white paper, *Choosing Health*, which continues the policy commitment to addressing inequalities in health, gives a high priority to tackling smoking, and also to supporting maternal and child nutrition in low income groups, primarily through the new Healthy Start scheme (Department of Health 2004).

Food support is offered to low-income women and their babies through the Welfare Food Programme in the UK; this programme is likely to be replaced by the new Healthy Start scheme in 2006/7. Information and guidance on breastfeeding and nutrition are available in the Sure Start local programme and Children's Centre areas to all families with young children.

1.4 Food-support programmes

1.4.1 The Welfare Food Scheme, UK

The Welfare Food Scheme was introduced in the UK in 1940 as part of the war effort to safeguard the nutritional status of pregnant women and young children (Department of Health 2002). Foods initially included in the scheme were liquid milk, national dried milk (NDM), concentrated orange juice and cod liver oil. Current entitlement includes one milk token per week that can be exchanged for 4 litres of liquid milk. Bottlefed infants less than 1 year of age are entitled to 900g formula from any of nine different brands of formula milk. Pregnant and breastfeeding mothers, and children under 5, receive free vitamins in the form of drops or tablets. Vitamin drops for pregnant women and breastfeeding mothers contain vitamins A, D and C, while tablets for breastfeeding mothers have calcium and iodine in addition to these vitamins (Department of Health 2002). Health promotion and nutrition education are not components of this scheme.

The Welfare Food Scheme was universal for all pregnant and lactating women and children aged less than 5 years. Later the emphasis shifted from universal provision to targeting those on social security. Therefore, social security eligibility is used by the Welfare Food Scheme as a proxy for nutritional risk.

Currently families in receipt of Income Support or Income-based Jobseeker's Allowance, expectant mothers and children below the age of 5 receive the entitlements free of charge.*

Young women below the age of 16 can claim welfare foods only if their parents are receiving Income Support

*** The scheme has been expanded to include those in receipt of child tax credit with an income below a threshold (£13,480 for 2004/5).**

or Jobseeker's Allowance; they cannot claim in their own right. Under the scheme, an unemployed 16–17 year old is entitled to receive Income-based Support (and therefore welfare food) if forced to live away from home and if she meets a number of hardship conditions. Otherwise 16–17 year old women are entitled to Income Support (and therefore welfare food), but only within 11 weeks of the expected date of delivery. Asylum seekers are not beneficiaries of this scheme.

The total cost of the Welfare Food Scheme was about £167 million for the year 1997/98, of which the cost of food was about £154 million and administration £13.5 million. Currently, approximately 800,000 women and children are enrolled in the scheme.

There has been no scientific evaluation of the scheme. However, a stakeholder review was undertaken by the Panel on Maternal and Child Nutrition of the Committee on Medical Aspects of Food and Nutrition Policy (COMA) in 1999 ((Department of Health 2002). The panel was of the view that although there was great potential for improving the health of nutritionally at-risk women and children through the scheme, there were major problems with it. Importantly, it did not meet the wider nutritional needs of pregnant women and young children. Failure to meet the nutritional needs of women increased their risk of lower uptake of periconceptional folic acid supplements, poor dietary intakes during pregnancy and vitamin D deficiency.

Equally important, the scheme inadvertently acted as a disincentive to breastfeeding. Breastfeeding mothers received only 7 pints of liquid milk, whereas non-breastfeeding mothers were entitled to receive 900g of infant formula, which was distributed by NHS staff. The scope for breastfeeding promotion was limited by the lack of contact with people who would provide advice about infant feeding, as tokens were sent directly to women or they were collected through post offices. It was noted that the scheme provided more milk/formula than was needed by young children and it did not promote awareness or uptake of vitamins. Uptake rates of vitamin supplements were reportedly low, particularly among low-income households (Department of Health 2002).

As a result of recommendations of the COMA review the scheme is undergoing major changes under the new name of Healthy Start. The key changes are:

- widening the nutritional basis of the scheme by the addition of fresh fruit and vegetables to the current entitlement of milk and formula
- replacing the token with a fixed-value food voucher
- running a public education and information campaign on the importance of good nutrition
- registering for the scheme at the time of the first ante-natal visit through a healthcare professional.

1.4.2 The WIC programme, USA

A White House conference in 1969 on food, nutrition and health recommended that pre-school children and pregnant women be given priority for nutrition programmes; this was the basis of authorising the WIC programme as a 2-year pilot project in 1972 (Kennedy 1999). The WIC programme has three main components: food supplementation, nutrition counselling and referral to health and social care services. The food package is designed to supplement the normal diet of the recipient (pregnant or postnatal woman or a child) rather than replace part or all of it.

Women are given fixed-value food vouchers, which are exchangeable for a basket of food at participating food stores (Besharov and Germanis 2000). Vouchers for 1 to 3 months are issued at WIC outlets. The food basket is designed to provide nutrients that are known to be lacking in the diets of women; foods are rich in protein, calcium, iron, and vitamins A and C. WIC foods for pregnant women currently include iron-fortified adult cereal, vitamin C-rich fruit and/or vegetable juice, eggs, milk, cheese, peanut butter, dried beans or peas, tuna fish and carrots. See the US Department of Agriculture's Food and Nutrition Service website, www.fns.usda.gov/fns

The food basket can be tailored to an individual's needs; for example, women with high cholesterol are likely to receive less eggs and peanut butter and more skimmed milk. Certain 'medical' foods may be provided when prescribed by a physician or a health professional for a specified medical condition. At the time of WIC certification a woman is offered at least two nutrition-counselling sessions. However, women may opt out of taking one or both of the sessions.

WIC is mandated to provide referral to other social and healthcare services as and when the need arises for participants. Referrals can be made for smoking cessation, family planning and prenatal care. Benefits continue until 1 year after childbirth if women are breastfeeding, and for 6 months postpartum if they are not. Typically, WIC is administered through healthcare organisations with arrangements varying from state to state.

Proxies for nutritional risk in this programme are financial, dietary and anthropometric measures. For the financial year 2004/05, to be eligible by income the household income had to be ≤ 185%* of the United States poverty income guideline before taxes were withheld. For example, a woman would be eligible for WIC if she was living in a two-person household with a gross annual income of $23,107 before taxes; this figure rose by approximately $5883 with every additional person in the household (see www.fns.usda.gov/fns).

Anthropometric risk criteria are based on evidence that a particular variable is amenable to change and measurement as a result of the WIC programme. These include low pre-pregnancy weight, low and high maternal weight gain, weight loss during pregnancy, and postpartum underweight and overweight. Maternal short stature is not used as an indicator of risk.

The following are used routinely to assess nutritional risk:

- biochemical risk criteria (including anaemia)
- medical conditions including conditions related to the intake of specific foods
- conditions relating to pregnancy (including age, parity, history of low birth weight, preterm birth, neonatal loss, late prenatal care)
- dietary risk factors (including food insecurity, failure to meet dietary guidelines, infrequent breastfeeding).

'Inadequate diet' as such is not used as a risk indicator. Predisposing risk criteria (including homelessness and migrant status) are also considered. The risk criteria were tightened considerably after a review conducted by the Institute of Medicine in the mid-1990s (Institute of Medicine 1996).

There are a few important aspects of WIC that are worth noting. First, it is a federally (centrally) funded grant programme for which the United States Congress authorises a specified amount of funds each year. It is administered at the federal level by the Food and Nutrition Service of the United States Department of Agriculture (USDA), and at the state level by WIC state agencies through authorised retailers.

Second, WIC is not an entitlement programme. This means that the federal government does not set aside funds for every eligible woman/child. Therefore not all people who are eligible for WIC receive the service.

Third, WIC is a $4 billion programme serving over 7 million women and children (see www.fns.usda.gov/fns). This figure includes over $1 billion saved to the government as a result of rebates provided (under pressure) by infant formula manufacturers – state WIC agencies pay on an average 85% less than the wholesale price for infant formula (Oliveira et al. 2002). An average food package in 1997 was worth about $46 a month, against an average cost to the government of about $32.

Fourth, the total average monthly cost of a WIC food package provided to a mother and her newborn can exceed $100 a month at 1997 rates.

Fifth, the United States General Accounting Office estimated that every federal dollar spent on prenatal WIC returned $3.50 in savings, primarily in reduced healthcare costs (US General Accounting Office 1992). These estimates were based on a number of influential evaluation studies conducted since the inception of the programme. The studies were typically conducted retrospectively, linking WIC records with birth and other records.

Finally, it is important to note that WIC has always been intended to serve as an adjunct to healthcare, in that it works alongside healthcare services to improve health outcomes for women and their children. It is not a stand-alone programme from the United States Department of Agriculture.

There have been numerous evaluations of the WIC programme since its inception.

*** United States Federal Government Household Poverty Guideline for 2004 for a household of four was $18,850 per annum in the majority of States. According to the WIC eligibility guidelines, a household of four with an income of $34,872 (≤ 185% of $18,850) would be eligible to claim WIC benefits.**

1.4.3 Expanded Food and Nutrition Education Programme (EFNEP), USA

EFNEP is a federally-funded nutrition education programme conducted through the Cooperative Extension Service (CES) in every state and territory of the USA since 1969. It is designed to assist people on low income to acquire the skills, attitudes and behaviour changes necessary for their diets to be nutritionally adequate, and to contribute to their personal development and the improvement of household diet and nutritional wellbeing.

Increasing an individual's self-worth is one of the key aims of this programme. Low-income youth and families with young children (including pregnant women and teenagers) are the targets, and the programme aims to improve food resource management, nutrition practices and food safety. Breastfeeding promotion is also a key focus of EFNEP.

It is delivered as a series of lessons over several months by professionals and lay volunteers. The approach is hands-on, learn-by-doing, and allows participants to gain practical skills necessary for behaviour change. This programme reached 164,000 adults and 447,000 young people in 2001. EFNEP cooperates with WIC, Food Stamp and a range of other government and non-government programmes.

1.5 Existing reviews

Several Cochrane reviews provide evidence of the effectiveness of nutritional supplements for childbearing women. Two reviews compiled evidence of the effectiveness of maternal nutrient supplementation for suspected impaired fetal growth (Merialdi et al. 2003; Say et al. 2003). Two others reviewed nutritional interventions for the prevention of maternal morbidity and pre-term delivery (Kulier et al. 1998; Villar et al. 2003). Other reviews have examined the effect of specific macro- and micro-nutrient supplements on key maternal and perinatal outcomes (Attalah et al. 2002; Kramer and Kakuma 2003; Mahomed 1997a/b/c, 1999; Mahomed and Gulmezoglu 1997, 1999; Makrides and Crowther 2001; van den Broek et al. 2002). These Cochrane reviews include studies from low- and high-income countries. None examined the effectiveness of national food-support programmes.

Van Teijlingen et al. (1988) examined the effectiveness of interventions to promote healthy eating in pregnant women and women of childbearing age. The outcomes of interest were changes in knowledge, attitudes and behaviour among participant women. While it included health promotion interventions that are of interest in this review, it did not study outcomes of interest, ie birth weight and other key perinatal outcomes.

Owen and Owen (1997) conducted a review of WIC studies. They included both prospective and retrospective studies but this review includes only prospective studies.

A more recent 'review of reviews' of public health interventions in relation to low birth weight studied smoking cessation and nutrition interventions targeting pregnant women (Bull et al. 2003). While the interventions and the outcomes are of interest to this review, the authors found no good quality systematic review of WIC or any other food-support programme targeting low-income childbearing women.

This current review therefore addresses this gap in the evidence base – the effectiveness of food-support programmes targeting low-income and socially disadvantaged women, with a view to improving perinatal and other health outcomes.

2 Aims of the review

This review was commissioned by the Health Development Agency (HDA) as part of the work of the Public Health Collaborating Centre for Maternal and Child Nutrition. It is published by the National Institute for Health and Clinical Excellence (NICE) after the HDA's functions were transferred to NICE on 1 April 2005.

2.1 Review question

What is the effectiveness and cost-effectiveness of food-support programmes for low-income and socially disadvantaged childbearing women that aim to have an impact on low birth weight and other outcomes related to maternal and infant nutrition?

2.2 Objectives of the review

- To study the effectiveness and where possible the cost-effectiveness of food-support programmes in improving low birth weight and other physical and psycho-social health outcomes for low-income and socially disadvantaged women and their babies.
- To identify which components of existing programmes that aim to improve nutrition of childbearing women show signs of success.
- To identify which programmes or their components are effective for particular groups of women.
- To identify any adverse effects of food-support programmes.
- To explore the potential of food-support programmes to reduce the health inequalities of mothers and their babies.

This review is relevant to policy in England and Wales.

3 Scope and methods of the review

A systematic review of the literature was undertaken.

3.1 Criteria for inclusion

3.1.1 Participants and settings

Studies of childbearing women* in developed country settings are included in this review. In particular, studies of women who are socially disadvantaged by virtue of their income, age, ethnicity and area of residence were eligible for inclusion. If a study happened to involve high-income women then it was included on the condition that separate results were available for high- and low-income women. Women may have been recruited to a study during pregnancy, in the postpartum period, in the inter-pregnancy interval, or during the periconceptional period. Studies concerning women who are in need of a special diet as a result of a medical condition (eg diabetes mellitus) are excluded. Studies conducted in developed country** settings are included; those conducted in low-income/developing countries are excluded.

3.1.2 Types of intervention

Food-support programmes for childbearing women are defined as those interventions that aim to improve nutritional intake among women, and/or the nutritional and health status of mother and newborn. Programmes including any or all of the following components are included in the review:

* The term 'childbearing' in this review refers to women who were in the childbearing age range.
** Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, United States. (Source: World Bank (2001) *World Development Report*. Oxford: Oxford University Press.

- food supplements in the form of either raw ingredients or prepared meals
- fixed-value food vouchers or tokens exchangeable for food items, and food stamps
- income support exclusively for food purchase
- ways of altering dietary intake in terms of both quality and quantity, ie nutrition education, advice and counselling.

Complex health and social care interventions that include all or some of the above are included in the review; they may also have other components such as social and practical support, and micro-nutrient supplementation.

For the purpose of this review, studies of the effects of specific vitamin and mineral supplements are excluded because updated good quality systematic reviews of effectiveness of macro- and micro-nutrients are available from the Cochrane Database of Systematic Reviews. Health promotion interventions that aim to encourage women to take foods rich in key vitamins/minerals are included. Multivitamins as a subsidiary component of food-support programmes are also included.

Outcomes

Primary outcomes

The primary outcome of interest is low birth weight – a reduction in the proportion of births below 2500g. However, studies do not always report a specific outcome labelled low birth weight; instead, they may use a range of outcomes, including birth weight and gestational age at birth. To decide on whether or not a study would be included, the following outcomes were used as probable indicators of low birth weight:

- mean birth weight
- gestational age at birth
- pre-term birth
- perinatal and infant mortality
- change in maternal weight
- maternal nutritional status.

Any significant difference in mean birth weight between groups was considered important.

Secondary outcomes

Secondary outcomes of interest are:

- participation rates in welfare programmes
- dietary intakes of nutrients
- health, wellbeing and pregnancy outcomes in subsequent pregnancies
- maternal anaemia (prenatal/postnatal)
- pregnancy induced hypertension (PIH)
- length of labour
- instrumental delivery
- maternal blood loss
- Apgar scores
- admission to a special care baby unit (SCBU)
- maternal and infant infections
- postnatal depression
- maternal exhaustion
- infant/child health indicators
- educational and behavioural outcomes in the child of a first pregnancy.

Changes in knowledge among participants, changes in women's food choices, and views of women and staff delivering programmes (if reported) are included. Key service delivery issues such as service outlets, mechanisms for delivery, criteria for inclusion/exclusion to a programme or success of the programme, and monitoring are studied if reported.

It must be noted that studies may not have been powered to detect differences in our outcomes of interest.

3.1.4 Study design

Evaluation studies employing the following designs were included in the review:

- randomised controlled trials (RCTs)
- non-randomised controlled trials (CTs) with concurrent controls
- before-after studies of cohorts or different groups
- cost-analysis studies.

Studies were excluded if they were not conducted prospectively or if control groups were selected retrospectively. Cost-effectiveness studies of large-scale food-support programmes are included as a separate section in the review (see section 4.5).

3.2 Identification of literature

The following bibliographic databases were searched:

- CAB Abstracts
- CINAHL
- Cochrane Central Register of Controlled Clinical Trials (CENTRAL)
- Cochrane Database of Systematic Reviews
- DARE
- EMBASE
- Food Science and Technology Abstracts
- HealthProm*is*
- MEDLINE
- PscyINFO
- Science Citation Index
- SIGLE
- SOCABS
- Social Science Citation Index
- Trip Database plus

Details of the search strategy for MEDLINE, the interface used, database coverage, search date and numbers of records retrieved can be found in Appendix 1.

Unpublished studies were not identified because of time constraints.

3.3 Data handling

Titles and abstracts identified through the search (approximately 9500) were assessed for relevance by one reviewer and independently checked by a second reviewer. By this process 348 potentially relevant studies were identified and hard copies of all were retrieved through networked sources, local libraries and interlibrary loan from the British Library. In the case of theses, short summaries were printed out via Dissertation Abstracts International (DAI) and checked for relevance by two reviewers.

A pre-screen form was developed on the basis of inclusion criteria for this review (see Appendix 2). Each study was independently assessed by one reviewer and decisions checked by another reviewer. Any disagreements were discussed, or referred to a third reviewer for resolution. Decisions were marked as either 'pre-screened and rejected', or 'for data extraction'. Classification was done only after all studies were assessed. Classification is as follows:

- evaluation studies of WIC
- studies of stand-alone nutrition supplements
- nutrition education/counselling/advice
- complex health and social care interventions including at least one nutrition component
- cost-effectiveness studies of national food-support programmes.

Data were entered onto a database designed specifically for the review. Tables were then generated in a structured format. Data extraction tables are presented in Appendix 3, one table per study. A second reviewer independently checked each table. Table 1 gives information on studies identified, excluded and included.

Table 1: Numbers of included and excluded studies

Number of citations identified through electronic search	9222
Number of citations meeting some inclusion criteria	348
Numbers of papers retrieved and pre-screened	348 (3 duplicates)
Number of intervention studies identified through secondary search	3
Intervention studies identified (total)	38
Intervention studies rejected on basis of design	19
Total intervention studies included	19
Total economic studies included	12
Total included studies	**31**
Total excluded studies	**317**

* See Section 6.4 for a discussion of excluded studies and Appendix 6 for the list of excluded studies.

3.4 Quality assessment

Study quality was assessed only after inclusion; none were excluded on the basis of quality assessment. The quality of each study was assessed using guidance in *Undertaking systematic reviews of research on effectiveness. CRD's guidance for those carrying out or commissioning reviews,* first by one reviewer and then independently by a second reviewer (Centre for Reviews and Dissemination 2001). Any disagreements were discussed and/or referred to a third reviewer.

Quality was assessed for RCTs and non-randomised controlled trials using the following questions.

- Were inclusion/exclusion criteria specified?
- Was sample size calculated a priori?
- Was the method of group allocation in controlled trials appropriate?
- Was the assignment to groups in RCTs truly random?
- Were groups comparable at baseline?
- Were outcome assessors blinded to group allocation at outcome assessment?
- What were the number and reasons for withdrawals and losses?
- Was analysis by intention-to-treat?
- Was the method of dietary assessment appropriate?

In the case of before-after studies the following questions were used:

- Were the groups selected from a suitable sampling frame?
- Were both groups selected from the same sampling frame?
- What was the sampling method used (random or other)?
- Were inclusion/exclusion criteria specified?
- Was sample size calculated a priori?
- Was adjustment made for possible confounding factors?
- Was analysis appropriate?
- Was the method of dietary assessment appropriate?

See Appendix 4 for quality assessment tables.

3.5 Strength of evidence

Each study was given a rating denoting the strength of evidence (–, +, or ++) according to the extent to which the quality criteria were fulfilled (see Table 2). Studies meeting few or none of the quality criteria were given less weight than those meeting all or most of the criteria.

Table 2: Grading of evidence*

++	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

3.6 Assessment of economic studies

A checklist drawn up for submissions to the *British Medical Journal* (on which the CRD's guidelines for evaluating economic studies are based) was used as a guide to assessing the quality of economic studies (Drummond and Jefferson 1996).

3.7 Synthesis

A narrative approach was adopted for the synthesis of study findings. Meta-analysis was not feasible because of the different study designs. The synthesis of included studies is presented in the following section under five categories:

- WIC evaluations
- trials of stand-alone supplemental nutrition interventions
- studies of nutrition education/counselling interventions
- complex health and social care interventions
- cost-analysis studies.

4 Results of the review

Studies included in the review

A total of 19 studies evaluating food-support type programmes and 12 cost-analysis studies met the inclusion criteria for the review. Intervention studies meeting the review criteria were classified as follows.

- Evaluation studies of the WIC programme, a complex healthcare intervention in which the key component is food supplementation;* this is linked with nutrition education and referral to health and social care. WIC is available on certification for women at nutritional risk during pregnancy and the postpartum period.
- Evaluations of stand-alone nutritional supplements** for women at nutritional risk during pregnancy.
- Evaluations of interventions in which the key component is nutrition education or nutrition counselling; participants in these studies were not exclusively low-income.
- Evaluations of complex health and social care interventions in which one – albeit minor – component was nutrition-related.
- Cost-analysis studies of national food-support programmes (WIC, EFNEP).

Table 3 below gives a summary of studies by intervention type and design.

Table 3: Included studies by intervention type and study design

	RCT	Non-randomised CT	Before-after	Total
WIC evaluations	1	4	1	6
Studies of stand-alone supplements	1	2	–	3
Nutrition education studies	4	3	1	8
Complex health and social care intervention studies	2	–	–	2
Total intervention studies	8	9	2	19
Cost-analysis studies	–	–	–	12
GRAND TOTAL	8	9	2	31

* Supplements in this type of intervention are actual foods, ie cereals, milk, eggs etc; they are more likely to be shared by other household members.
** Supplements in this type of intervention are nutrients from one or more of the main food classes (carbohydrate, protein, fat) and provided in a form other than food, ie as a drink; they are less likely to be shared by other household members.

4.1 Results of studies evaluating the special supplemental nutrition programme for women, infants and children (WIC)

4.1.1 Number of WIC studies

Six evaluation studies of WIC were identified. Two were large-scale national evaluations (Edozien et al. 1979; Rush et al. 1988 – the first and second WIC national evaluations). See Table 4 for a summary of studies, and for data extraction see Tables 1–6, Appendix 3.

4.1.2 Characteristics of participants

Intervention group (WIC) participants in all six studies were, as expected, low-income women, certified to be at nutritional risk for poor health outcomes. In three studies control group women were from better-off households (Collins et al. 1985; Metcoff et al. 1985; Rush et al. 1988), while in the other three they were reported to be in the same income group (Bailey 1983; Edozien et al. 1979; Pehrsson et al. 2001). Many of the women were also receiving other welfare benefits. For example, just under half of the study group participants in the national evaluation by Rush et al. (1988) were on food stamps and/or Aid to Families with Dependent Children (AFDC). Many of the participants in other studies had, or were eligible for, Medicaid cover.

- The mean age of study participants was between 21 and 25. The percentage of young women (< 18 years) was reported in one study to be 25% and 28% in the intervention and control groups respectively (Bailey 1983).
- The ethnic composition of groups varied from study to study. The first national WIC evaluation included just over 74% women from minority ethnic groupings (Edozien et al. 1979). Between 21% and 62% women were identified as 'black' in the smaller studies.
- Educational attainment was low; participants had between 9 and 12 years of education.
- Some studies reported figures for married women of between 42% and 57%.
- Not all studies reported smoking habits of participants at entry; where they did the proportions varied from 7% to 56%.
- A history of delivering a low birth weight baby in the past varied from 6% to 22%, although these data were not reported for all six studies.

4.1.3 Characteristics of the WIC programme

Although only two papers described the intervention in detail, it can be assumed that it was broadly the same in all six studies. Pregnant and lactating women participating in the WIC programme were given vouchers or cheques that could be exchanged for a monthly food basket consisting of milk (29.33L) or cheese (453g in lieu of 2.83L milk); eggs (30); cereal (4 x 226g packs); and juice (6 x 1.36L cans). The cereal contained ≥ 45% recommended daily allowance (RDA) of iron and ≤ 6g sucrose for 28g dry weight of cereal. At that time cereal was not fortified with folic acid. This food basket was meant to supplement the normal diet of poor women, and not to replace it.

Nutrition education in the form of classes, counselling and other activities to teach participants about proper nutrition, positive food habits and prevention of nutrition-related health problems was offered to each participant at the time of certification. Breastfeeding promotion and support was a key part of the programme. Women were also offered information and referral to other health and social care services such as immunisation clinics, and the Medicaid and Food Stamp programmes for vulnerable households. Section 1 provides a more detailed description of the WIC programme.

4.1.4 Outcomes measured

All the studies bar Pehrsson et al. (2001) were of WIC participation in pregnancy and measured mean birth weight (MBW) and all except one (Edozien et al. 1979) of these measured rates of low birth weight. Two studies (Collins et al. 1985; Metcoff et al. 1985) conducted separate analyses of mean birth weight for babies of women who smoked at the time of entry to the study. Other outcomes were as follows.

- Rush et al. (1988) was the only study reporting on head circumference at birth; this national evaluation also measured programme quality.
- Dietary intake of energy, proteins and selected vitamins (in particular iron and folic acid) were measured in four papers (Bailey 1983; Edozien et al. 1979; Pehrsson et al. 2001; Rush et al. 1988).
- Pehrsson et al.'s study of non-lactating postpartum women measured haemoglobin, plasma ferritin and transferrin receptor. Some or all of these biochemical indices and/or rates of anaemia, and serum iron and

Table 4: Summary of WIC studies

Author, year	Design	WIC participants	Controls	Sample size	Outcome measures	Strength of evidence	Key findings
Bailey 1983	CT	WIC participants in Florida, USA	Women attending public health clinics in adjoining county; not in WIC	89	LBW; MBW; serum iron, folate, transferrin, haematocrit	–	Differences in LBW, MBW between groups not significant
Collins et al. 1985	CT	WIC participants in Alabama, USA	Women attending public health clinics, same area – more affluent; not in WIC	519	MBW, maternal weight gain, health and nutrition-related knowledge and practices	–	Differences in MBW between groups not significant
Edozien et al. 1979	Before-after	WIC participants in 14 states, USA	Women in same 14 states, low-income, not in WIC	9867	MBW, gestational age at birth, IUGR; pre-term birth, weight gain in pregnancy, dietary intake	–	Differences in MBW between groups not significant
Metcoff et al. 1985	RCT Computerised random numbering	WIC participants attending prenatal clinics, Oklahoma	Women attending prenatal clinics not in WIC	410 (not clear)	LBW, MBW, gestational age at birth, biochemical indices	+	Differences in LBW between groups not significant; overall differences in MBW not significant; babies born to smokers in WIC group significantly heavier than babies born to control group smokers
Rush et al. 1988	CT	Women attending WIC clinics in counties across the USA	Women attending prenatal clinics in counties where WIC had not yet started	6563	LBW, MBW, maternal weight gain, head circumference at birth infant growth, nutrient intake choice of infant feeding method, other outcomes	+	Differences in LBW, MBW, duration of gestation between groups not significant; significant reduction in early pre-term births < 33 weeks in WIC group; higher energy and protein intake in WIC group; significantly higher maternal weight gain in WIC group; head circumference larger in babies of WIC participants; better programme quality linked to accelerated fetal growth, lower rates of LBW and larger head circumference
Pehrsson et al. 2001	CT	Women who had participated in WIC during the last pregnancy; re-certified for WIC participation in the postpartum period	Women who had participated in WIC during the last pregnancy but NOT re-certified in the postpartum period	110	Haemoglobin concentrations, transferrin level, ferritin level	+	Haemoglobin concentration of WIC women increased with longer participation reaching statistical significance at 6 months

CT = controlled trial RCT = randomised controlled trial LBW = low birth weight (< 2500g) MBW = mean birth weight IUGR = intrauterine growth retardation

folate were reported in the other five studies.
- Maternal weight change was measured in four studies (Collins et al. 1985; Edozien et al. 1979; Metcoff et al. 1985; Rush et al. 1988).
- Only one study reported pregnancy and nutrition-related knowledge and practices (Collins et al. 1985).
- Rush et al. (1988) reported on breastfeeding intention and breastfeeding at hospital discharge.
- Apgar scores and newborn ponderal index (birth weight in g/crown-heel length in cm) were reported in Bailey (1983).
- Two studies including a national evaluation reported on complications of pregnancy such as vaginal bleeding and premature rupture of membranes (Collins et al. 1985; Rush et al. 1988).

4.1.5 Methodological quality of included WIC studies

Of the six studies included in this section of the review, one was an RCT, four were CTs* and one was a before-after study. Sample size ranged from 89 to 9867. Inclusion criteria were clear in all except one paper (Edozien et al. 1979). Overall the quality of the WIC studies was not good.

Groups were not comparable at baseline in three of the six studies – women in the control groups were better off than the WIC group (Collins et al. 1985; Metcoff et al. 1985; Rush et al. 1988).

Of all the studies only the 1988 national WIC evaluation by Rush et al. discussed sample size calculation; however, it did not recruit the desired number of women to the control group. Furthermore, one quarter of the women in the control group at study entry crossed over to the WIC group. Analysis was done both ways – ie according to the group allocation at study entry when there were only two groups (WIC and control), and according to group at follow-up when there were three groups (WIC, WIC-Control and Control).** The final sample had a power of 0.25 to detect a difference of 30g mean birth weight at an $\propto$ level of 0.05. Other outcomes such as maternal weight gain, dietary intake and pregnancy complications were reported in this large-scale national evaluation.

In the RCT (Metcoff et al.), the method of randomisation was true. Blinding at outcome assessment was not used or not reported in any of the trials. Rush et al. discussed withdrawals and losses in detail, giving reasons by group, and Pehrsson et al. gave numbers lost but without reason, while others did not provide any such detail.

The largest of the WIC evaluations (sample size 9867) appeared to be a before-after study, in that the mean value for a group was compared to the initial value obtained at the time of enrolment (Edozien et al. 1979). This was a poorly reported study – the paper does not give a clear account of the sampling method; inclusion and exclusion criteria for study entry are not clear; and withdrawals and losses are not reported adequately. Intention-to-treat method of analysis was followed only in Rush et al. (1988), the second national evaluation. None of the studies provided detailed information about the timing of smoking cessation. The conclusions from these studies need to be interpreted with caution.

4.1.6 Dietary assessment methods

Four of the five studies of prenatal WIC participation used 24-hour recall to estimate dietary intake. The fifth study (Collins et al. 1985) made no mention of assessing dietary intake. Not all studies mentioned who collected these data.

- Rush et al. used trained field workers. In this study 75% of participants were interviewed about their diets at study entry and the same women were interviewed at follow-up (36 weeks).
- Edozien et al. obtained 24 hour dietary intakes from 'half the sample' at entry and at follow-up.
- Pehrsson et al.'s study of postpartum WIC participation used a self-administered low-literacy food frequency questionnaire designed to rank consumption of foods contributing to iron and vitamin C intake relative to other participants (rather than measuring actual intakes). The authors state that the instrument had poor sensitivity. Intakes were generally reported as both means and percentages of the recommended daily allowance (RDA).

Rush et al. (1988) is the only study in this group that tested the reliability of the 24 hour recall; they conclude that any reported differences in intake would tend to be

* CT = controlled trial; RCT = randomised controlled trial.
** There were three groups in this study:
- WIC group – participants who were assigned to the WIC group and remained in the group until the end of the study
- Control group – participants who were assigned to the control group and remained in that group until the end of the study
- WIC-Control group – participants who were assigned to the control group but crossed over to the WIC group later in the study.

under-estimates rather than over-estimates.

4.1.7 Effectiveness of WIC

See Appendix 7 for evidence of effectiveness.

Rates of **low birth weight** were reported in one large-scale national evaluation and three smaller studies of prenatal WIC participation.

- Bailey and Collins et al. made no mention of adjusting for gestational age.
- Metcoff et al. stated that pre-term birth was not taken into account when reporting on rates of low birth weight.
- Rush et al. made adjustments for gestational age at birth.
- Bailey reported low birth weight rates of 5% and 10%, Collins et al. 6.4% and 3.8%, Metcoff et al. 6% and 8.8% and Rush et al. 7.4% and 7.6% for WIC and control groups respectively; these differences did not reach statistical significance.

The higher quality studies (Metcoff et al. 1985; Rush et al. 1988), both of which show small but not statistically significant differences in favour of the WIC group, provide moderately strong evidence that prenatal WIC participation has no significant impact on reducing rates of low birth weight.

All five studies of prenatal WIC participation report on **mean birth weight**.

- Edozien et al., Metcoff et al. and Rush et al. adjusted birth weight for maternal weight at entry to the programme, gestational age at birth and smoking; Bailey and Collins et al. did not report such adjustments.
- Bailey found that babies in the WIC group were 47g lighter than in the WIC group, but this difference did not reach statistical significance.
- Collins et al. found that mean birth weight was the same for both groups at 3200g.
- Edozien et al. found a statistically significant increase of approximately 68g in mean birth weight among babies born to mothers who participated in WIC for 36 months during a first pregnancy. An observed difference of about 5 days in duration of gestation is likely to have influenced mean birth weight. It is notable, however, that the study did not meet many of the quality criteria for this review.
- Metcoff et al. found that an initial difference of 91g in mean birth weight was not significant at $p < 0.05$ when maternal weight at entry was factored into the analysis.
- Rush et al. found that in the central analysis mean birth weight of WIC babies was 7g less than babies of mothers who were in the control group at study registration.

It must be noted that the final sample in Rush et al. was smaller than had been originally planned and the power of this study to detect a difference of 30g birth weight as a result of WIC participation at an $\propto$ level of 0.05 was only 0.25, ie if there was an actual birth weight effect of 30g there was a 75% chance of accepting the null hypothesis if it was not true.

The higher quality studies provide moderately strong evidence that prenatal WIC participation has no significant effect on mean birth weight (Metcoff et al. 1985; Rush et al. 1988).

Two studies reported on the impact of prenatal WIC participation on mean birth weight of babies born to **smokers**.

- Bailey found that the large difference (485g) observed between babies born to smokers and non-smokers in the control group was not seen in the WIC group – the difference went down by 417g.
- Metcoff et al. found that babies born to women in the intervention group who smoked more than 10 cigarettes a day were 168g heavier ($p < 0.01$) than those in the control group after adjusting for the number of prenatal visits, maternal weight at entry to the programme and inter-pregnancy interval.

The higher quality study suggests that prenatal WIC participation may have a beneficial effect on mean birth weight of babies born to heavy smokers (Metcoff et al. 1985). Whether this is directly attributable to WIC food supplementation or to a smoking cessation intervention is not clear from the paper. Therefore this study gives only indicative evidence* that prenatal participation in WIC benefits babies born to mothers who smoke heavily during their pregnancy.

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* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

Gestational age and/or **pre-term birth** were reported in both national evaluations and one smaller study.

- The rates of pre-term birth reported in Collins et al. were 5.4% and 4.9% in the WIC and control groups respectively; these differences were not statistically significant.
- Edozien et al.'s evaluation found an increase of approximately 6 days of gestation between women who received prenatal WIC benefits for less than 3 months and those that received them for more than 6 months ($p < 0.05$). As noted earlier this study was of poor quality
- The second national evaluation, Rush et al., found an increase in the mean duration of gestation as a result of WIC, which was not statistically significant. The frequency of pre-term birth (< 37 weeks gestation) in the WIC group was 1.3% lower than in the control group, and very preterm (< 33 weeks gestation) birth was 0.9% lower; again these figures did not reach statistical significance.

It is notable that the power of Rush et al. (1988) to demonstrate a 1% difference from a baseline of 15% in the rate of pre-term birth was only 0.11 at the 0.05 significance level; the study was underpowered to measure accurately the impact on pre-term birth.

Only one study reported on **head circumference** at birth (Rush et al. 1988). The study found a small but statistically significant ($p < 0.01$) increase of 0.18-0.21cm with programme participation. It is notable that the increase in head circumference was not related to birth weight, and that this finding was incidental and not hypothesised at the planning stage of the study. This study provides moderately strong evidence of the effectiveness of WIC in increasing the head circumference of babies born to participating mothers.

Change in maternal weight was reported in four studies.

- Collins et al. found that women in the WIC group gained 11.7kg during a first pregnancy and those in the control group gained 11.3kg; this difference was not statistically significant.
- Edozien et al. reported a significant difference of 1.3kg between all pregnant women in the WIC and control groups ($p < 0.01$)
- Metcoff et al. found that WIC women weighed 2.5kg more at 36 weeks than the control group women ($p = 0.057$), after adjusting for differences in weight at entry to the study (19 weeks). However, there were no differences in weight gain per week
- In Rush et al.'s national evaluation, WIC women were found to be 0.72kg lighter at entry compared to control group women ($p < 0.01$), and WIC-Control* women were 0.87kg lighter ($p < 0.05$); these observations were adjusted for weight at the time of conception. Both groups participating in WIC had lower early pregnancy weight gain. By late pregnancy WIC participation brought the weights of WIC women up to the same level as control group women. This can be interpreted as a total higher weight gain among those who participated in WIC.

The WIC-Control group women, who crossed over to WIC later in Rush et al., actually put on weight after entering the programme, but they were still 0.27kg lighter than controls in late pregnancy. Maternal weight gain was lower for black women (Rush et al. 1988). Late pregnancy fat stores were lower among WIC women (Rush et al. 1988). There is moderately strong evidence from the two higher quality studies that earlier and longer participation in WIC is likely to have a greater impact on maternal weight gain weight (Metcoff et al. 1985; Rush et al. 1988).

Haemoglobin concentrations, and/or other indices of **iron and folate sufficiency** are reported in four studies.

- Bailey found no significant differences in haematocrit and serum iron; there were significant differences in transferrin saturation ($p < 0.05$) and serum folacin ($p < 0.05$).
- The first national evaluation, Edozien et al., found significant differences in the rates of anaemia between women entering the WIC programme after 28 weeks of pregnancy and their controls ($p < 0.05$); the same difference was noted among postpartum women ($p < 0.05$). As discussed earlier this study was not of good quality.
- The second national evaluation, Rush et al., reported increases in haemoglobin concentration by late pregnancy with WIC participation but this did not reach statistical significance. Late pregnancy haemoglobin levels were significantly lower among black women. Women who reported taking iron supplements did not have higher levels of haemoglobin in late pregnancy.

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* See footnote, p19.

- Pehrsson et al.'s study of non-lactating postpartum women found that haemoglobin concentrations increased in the WIC group over the first 6 months postpartum, at which point differences between WIC and control groups reached statistical significance ($p < 0.05$). Rates of anaemia reduced steadily in parallel with the rise in haemoglobin so that at 6 months differences in rates of anaemia between the groups were statistically significant ($p < 0.05$). The differences in ferritin and transferrin levels were not significant.

There is moderately strong evidence from Pehrsson et al. (2001) to suggest that uninterrupted WIC participation during the postpartum period has a beneficial effect on both haemoglobin concentration and rates of anaemia among non-lactating women.

Pregnancy complications, and abnormalities of labour and delivery were reported in two studies.

- Collins et al. reported no effect of WIC participation on pregnancy complications except for a significant difference in numbers of women with albumin in the urine ($p < 0.02$).
- Rush et al. studied a number of conditions including high blood pressure, haemorrhage and premature rupture of membranes. They found a significant reduction in the frequency of premature rupture of membranes between WIC and control groups ($p < 0.01$). Fever and infections were less in the WIC group but the differences were not significant.

Rush et al. (1988) provide moderately strong evidence of a reduction in premature rupture of membranes as a result of WIC participation.

Infant mortality, one of the outcomes of interest in this review, was not measured in any of the six included studies. Rush et al. measured **fetal mortality** and found differences of some magnitude between WIC and control groups. However, the numbers were too small in the final study sample to test fetal mortality separately.

When WIC was launched in the early 1970s food supplements were designed to provide protein, iron, calcium and vitamin C and A. Four studies reported on maternal **dietary intake** of a range of nutrients.

- Bailey reported significant increases in iron and vitamin B6 intakes in the WIC group.
- Edozien et al. reported increases in protein, iron, calcium, phosphorous, and vitamins B6 and C, but these were not significant.
- Pehrsson et al.'s study of postnatal WIC participation found no differences in dietary intakes of iron.
- Rush reported no differences in intakes of macro- and micro-nutrients in the three study groups at the initial interview.

In Rush et al., participation in WIC was associated with an increase in intakes of protein, iron, calcium and vitamin C (four of the five targeted WIC nutrients) and magnesium, phosphorous, thiamin, riboflavin, niacin, B6 and B12. Increments in caloric intake of the two groups (WIC and WIC-Control groups)* exposed to the WIC programme were 5.8% and 7.5%. There was a greater programme impact on energy intake for the heaviest smokers (> 15 cigarettes/day). No explanation is offered for this finding. There is moderately strong evidence that WIC participation results in an increase in a wide range of nutrients, particularly for those targeted by the programme.

Rush et al. also found that more WIC women than controls smoked cigarettes at study entry ($p < 0.05$) but this was reversed by the end of pregnancy. Collins et al. found no differences in rates of **smoking**.

Breastfeeding was reported in two studies.

- Collins et al. found that differences in rates of women planning to breastfeed were not significant.
- Rush et al. reported on breastfeeding intention as well as breastfeeding at hospital discharge. Fewer women in the WIC groups intended to breastfeed, and fewer breastfed at hospital discharge than control group women. However, after controlling for socio-demographic factors the differences in both breastfeeding intention and initiation fell and became non-significant.

It is important to note that both these studies were conducted before the federal mandate for breastfeeding promotion came into effect in the early 1990s. See two recent reviews of breastfeeding interventions for the effectiveness of WIC on breastfeeding initiation and duration (Fairbank et al. 2000; Renfrew et al. 2005).

Rush et al. reported on other outcomes such as number of **prenatal visits** and **nutrition counselling sessions**, and

* See footnote, p19.

changes in hours worked each week. WIC participation had no effect on frequency of prenatal care. There was no evidence that WIC participation enabled women to reduce the **time worked**. More WIC enrolled women than control group women had two or more nutrition education sessions ($p < 0.001$) and fewer WIC enrolled women than control group women had no sessions ($p < 0.001$). This study generated moderately strong evidence that WIC participation increases the number of women receiving nutrition education and the number of such sessions each woman receives. WIC did not have an impact on income transfer or on frequency of prenatal care.

Rush et al. also made observations about the impact of **programme quality** on perinatal outcomes. The study found that higher programme quality had beneficial effects on rates of low birth weight and newborn head circumference. Head circumference varied less (than low birth weight) with programme quality, suggesting that it might have been more directly related to food supplementation.

It is notable that WIC directors assessed programme quality and so there may have been an element of subjectivity in the assessments. Furthermore, there is not sufficient evidence from this paper as to which components of the programme (counselling, quality of nutrition education, individual care plans, or compliance with state and federal regulations) resulted in these associations. Rush et al. (1988) provides indicative evidence* that improving programme quality may have a positive effect on low birth weight and head circumference.

4.1.8 Summary of evidence of effectiveness of WIC

Six studies of WIC are included in this section of the review, five on prenatal WIC participation and one on postnatal participation. Three of the five prenatal studies met few quality criteria for this review, and only two studies provide reliable evidence on the effectiveness of prenatal WIC participation (Metcoff et al. 1985; Rush et al. 1988). Both of these studies provide moderately strong evidence that WIC did not have a significant impact on the primary outcome of interest – low birth weight.

- The authors of the second national WIC evaluation (Rush et al. 1988) did report a significant positive association between programme quality and rates of low birth weight. WIC directors assessed programme quality so this finding needs to be interpreted with caution.
- There is evidence from both the higher quality studies that WIC had no significant impact on mean birth weight (Metcoff et al. 1985; Rush et al. 1988).
- Metcoff et al. demonstrated a favourable effect of WIC participation on the birth weight of babies born to women who smoked heavily. Rush et al. did not find a reduction in smoking as a result of WIC. This suggests that any increase in birth weight of babies born to WIC mothers who smoked was probably not due to smoking cessation.
- Energy intake was higher among WIC women smokers.
- There is moderately strong evidence that head circumference (unrelated to increments in birth weight) increased as a result of participation in WIC.
- Gestational age at birth and the frequency of preterm birth was not influenced by WIC participation.
- WIC does not appear to have any significant positive impact on complications during labour and delivery except for reduction in rates of premature rupture of membranes.
- Rush et al.'s national evaluation did not generate evidence of a significant impact of WIC on fetal mortality.
- Dietary intakes for the majority of nutrients including protein, vitamin C, iron and folate increased among WIC groups. However, folate intake was noted to be below the RDA even towards the end of the pregnancy.
- Maternal weight gain is favourably affected by WIC participation.
- Haemoglobin and other iron and folate sufficiency measures reflected improvements in iron intake with participation in WIC.
- There is no evidence that WIC had an impact on breastfeeding initiation in hospital.
- More women were likely to receive nutrition counselling during pregnancy and have more than two counselling sessions if they participated in the programme.
- Evidence generated from the second national evaluation by Rush et al. suggests that women who participated in WIC did not reduce their working hours.

Only one study (Pehrsson et al. 2001) generated evidence of effectiveness of postpartum WIC participation. There is strong evidence from this study that uninterrupted participation in the programme for six months after delivery resulted in reducing the prevalence of anaemia

* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

4.2 Results of studies evaluating stand-alone nutrition supplement interventions

4.2.1 Number of studies

Three studies of stand-alone nutrition supplement interventions were identified (Rush et al. 1980; Viegas et al. 1982a/b). See Table 5 for an overview of the studies, and Tables 7–9 in Appendix 3 for data extracted.

4.2.2 Characteristics of participants

Participants in all three studies were from minority ethnic groups. The RCT (Rush et al. 1980) was a study of low-income black women in the USA. In this study, between 24.6% and 26.5% were welfare recipients at the time of the study. Mean age ranged from 21.5–21.9 in the three arms of the study. Protein intake was low in approximately half of all participants. Groups were comparable at baseline. In the two other studies (Viegas et al. 1982a/b) participants were Asian women living in the UK; they were of Pakistani, Indian or Bangladeshi origin. The second of these two studies recruited women who were identified as being at higher nutritional risk, defined as ≤ 20mm/week increment in triceps skin fold thickness during the second trimester.

4.2.3 Characteristics of the interventions

In the USA study the first experimental group received a high protein supplement consisting of two eight ounce cans a day of high protein beverage containing 40g animal protein and 470 calories; the second experimental group received a balanced protein-energy supplement in

Table 5: Overview of stand-alone nutrition supplement interventions

Author, year	Design	WIC participants	Controls	Sample size	Outcome measures	Strength of evidence	Key findings
Rush et al. 1980	RCT Method of randomisation not stated	Low-income black women in the USA	–	1051	LBW, MBW, maternal weight gain	++	Overall differences in MBW of term babies between groups not significant; babies of smokers in the intervention group significantly heavier than control group babies; differences in head circumference not significant; differences in maternal weight gain not significant; higher early neonatal mortality (25–29 weeks) in high protein supplement group
Viegas et al. 1982a	CT	Asian women in the UK	Fewer Hindus and Sikhs; higher mean weight and height	153	MBW, newborn skin fold thickness and MUAC, placental weight, maternal weight gain, skin fold thickness, MUAC and plasma proteins	–	Birth weight similar in supplemented and control groups; differences in maternal weight gain between 18–28 weeks significant; differences in maternal weight gain in third trimester not significant
Viegas et al. 1982b	CT	Asian women at nutritional risk in the UK	More Muslims from Pakistan, more consanguineous marriages, fewer vegetarians	130	MBW, gestational age at birth, newborn length and head circumference, placental weight	–	Crude birth weight significantly higher in at-risk supplemented group compared with at-risk unsupplemented group; differences in gestational age, length at birth not significant

CT = controlled trial RCT = randomised controlled trial LBW = low birth weight (< 2500g) MBW = mean birth weight MUAC = mid-upper-arm circumference the form of two eight ounce cans of beverage a day containing 6g animal protein and 322 calories. The control group and both intervention groups also received vitamins and minerals. The intervention was delivered at home by a specially trained health aide. It began at ≥ 30 weeks gestation and stopped at the birth of the baby.

In the UK studies one group received 3mg iron, 30mg vitamin C and a carbonated glucose drink providing 273kcal (1.1MJ) energy, while the other group received the same plus protein in 26g of a chocolate-flavoured powder. The control group received only the vitamins. Supplements were started in the 28th week and continued until the 38th week. Community midwives delivered the supplements to women's homes every 5 weeks. In addition a dietitian discussed the use of supplements on clinic visits. It is notable that the supplements, although supplied as a beverage, were medicinal in their presentation.

4.2.4 Outcomes measured

The North American study measured maternal intake of supplements, maternal weight gain during pregnancy and duration of gestation along with perinatal mortality. Infant weight, length, head and arm circumference and skin-fold thickness, and neurological measures of maturity were measured at birth. Both UK studies measured weight gain, skin fold thickness, mid-upper-arm circumference (MUAC), plasma proteins and ribonuclease activity in the mother; birth weight, skin fold thickness and MUAC in the newborn; and placental weight.

4.2.5 Methodological quality of studies of stand-alone nutrition supplement interventions

Rush et al. (1980) was an RCT and both the UK studies (Viegas et al. 1982a/b) were non-randomised CTs. Sample size ranged from 130 to 814 women and inclusion and exclusion criteria were clear in the RCT. Both CTs had clear inclusion, but not exclusion, criteria.

Groups were comparable at baseline in the RCT. In the CTs there were important differences between groups. For example, one of the three groups in the second trial had more Muslims from Pakistan and therefore more consanguineous marriages, and fewer vegetarians.
A priori sample size calculation was performed in the case of the RCT but not the two CTs.

Rush et al.'s RCT was powered to detect a 125g difference in mean birth weight at an $\propto$ level of 0.05. It is not clear what method of randomisation was used. There is not enough detail to ascertain how women were allocated to groups in the CTs; the first was designed to give the same distribution for parity, abnormal past obstetric history and vaginal bleeding in the current pregnancy. All three trials reported withdrawals and losses with reasons. Blinding at outcome assessment was used in the RCT, but there was no mention of blinding in the CTs. Analysis was by intention-to-treat in the case of the RCT, but not in either of the CTs – results from these two studies need to be interpreted with caution.

4.2.6 Dietary assessment methods

Rush et al. (1988) used 24 hour quantitative dietary recall by a nutritionist at recruitment, 2 weeks and 6 weeks, and at approximately 32 weeks gestation. The authors note that compliance was high. Both UK studies (Viegas et al. 1982a/b) also used 24 hour recalls, along with weighed diet periods of 3 to 7 days.

4.2.7 Effectiveness of stand-alone nutrition supplement interventions

See Appendix 7 for evidence of effectiveness.

The North American study found that differences between groups in rates of **low birth weight** were not statistically significant. Women who had delivered low birth weight babies in the past were more likely to deliver a low birth weight baby. The UK trials did not study low birth weight.

Findings concerning **mean birth weight** were different in the three studies. The North American study (Rush et al. 1980) found no significant differences in mean birth weight in the whole sample when gestational age was not factored into the analysis. However, sub-set analysis of pre-term births (< 37 weeks gestation) suggested that babies born to women in the high-protein supplemented group were significantly lighter than those in both the balanced protein-energy group ($p < 0.02$) and the control group ($p < 0.01$). The high protein supplement appeared to have caused **intrauterine growth retardation**. It is notable that there was no deficiency in dietary protein intake in either groups at baseline. This trial also found that babies of heavy smokers (≥ 15 cigarettes/day) in the supplemented groups were significantly heavier at birth compared with babies of smokers in the control group.

The first UK study (Viegas et al. 1982a) found no impact of the protein-energy-vitamin supplement on mean birth weight (crude birth weight). The second UK study (Viegas et al. 1982b), targeting high risk Asian women, found that nutritionally at-risk mothers who received the protein/energy/vitamin supplement had babies who were heavier at birth irrespective of gestational age. These differences were the same when study data were compared with datasets of babies born to women in Edinburgh and Birmingham. Both UK studies meet only few of the quality criteria of this review.

- In the USA study (Rush et al. 1980), balanced protein-energy supplementation given to black women resulted in an increase in the **length of gestation**, but high protein supplements caused very early **pre-term births**.
- Differences in gestational age at birth among high risk Asian women found in the second UK study were not significant (Viegas et al. 1982b).
- Rush et al. found that **neonatal mortality** was higher in the high-protein group but this did not reach statistical significance.
- Rush et al. also found that differences in head circumference were not statistically significant. The second UK study found significant differences ($p < 0.02$) in **head circumference** between babies born to supplemented and control group mothers in the low-risk group, but there were no similar differences in the high-risk groups.
- In the USA study (Rush et al.) differences in other somatic measures of infant health were not significant in the RCT. However, at 1 year a significant (favourable) effect was observed in **infant psychological health** in terms of visual habituation, visual dis-habituation and length of play episodes in babies born to mothers in the high-protein supplemented group.

The USA study and the second UK study found that overall there were no significant differences between groups in **maternal weight gain**. Women receiving the high-protein supplement from early in pregnancy gained more weight in early pregnancy ($p < 0.05$) than the balanced energy-protein group, but they lost this advantage and by the time they delivered they had markedly decreased weight gain (Rush et al. 1980). The first UK study, however, found that women in the protein-energy-vitamin group gained significantly more weight and fat between 18 and 28 weeks than the control group (Viegas et al. 1982a). There were significantly higher ($p < 0.05$) weekly increments in triceps skin fold thickness in the protein/energy/vitamin supplemented group than the control group, who got only vitamins.

There is strong evidence from Rush et al. (1980) that high protein supplements are very likely to result in intrauterine growth retardation and very early pre-term births among women who had adequate protein in their normal diets at study entry. This study generated strong evidence that a balanced protein/energy supplement is likely to increase the length of gestation, and that heavy smokers who receive supplements are likely to have heavier babies than those who do not. Infant psychological outcomes are likely to improve as a result of high-protein supplements.

4.2.8 Summary of evidence of effectiveness of stand-alone nutrition supplement interventions

Three studies are included in this section of the review. The USA study (Rush et al. 1980) met most of the quality criteria, while both UK studies met few quality criteria. There is strong evidence from Rush et al. that a balanced supplement containing protein and energy had no significant impact on rates of low birth weight among black American women. The evidence is similarly strong that babies born to heavy smokers who receive supplements containing protein and energy are heavier than those born to heavy smokers who have not received a protein/energy supplement. High-protein supplements resulted in impaired fetal growth and very early preterm births. Infants of mothers who received high protein supplements had significantly better psychological outcomes compared to balanced protein energy or vitamin only supplemented groups.

4.3 Results of nutrition education and/or counselling studies

4.3.1 Number of studies

Eight studies of nutrition education interventions targeting pregnant women were identified. Table 6 provides a summary of the included studies in this section. For data extracted see Tables 10–17, Appendix 3.

4.3.2 Participants and settings

One study was conducted in the UK, one in Canada, one in Greece and five in North America.

- Participants in all but one study were between 21 and 24 years of age. In the remaining study all participants were young women below the age of 20 (Long et al. 2002).
- Three studies recruited only women from minority ethnic groups – African-American (Briley et al. 2002), immigrants from Mexico (Hunt et al. 1976) and native-Americans from Cree communities in Canada (Gray-Donald et al. 2000).
- Three studies reported educational achievement of women (Briley et al. 2002; Hunt et al. 1976; Kafatos et al. 1989). Between 44% and 100% had less than high school education, with all women in Hunt et al. having less than 6 years' education.
- The majority of participants in four of the eight studies were reported to be in low-income groups (Briley et al. 2002; Hunt et al. 1976; Kafatos et al. 1989; Widga and Lewis 1999). In Hunt et al. all participants were in very low-income households (annual income < $6000).
- Between 46% and 100% of women in the three studies reporting marital status were single (Briley et al. 2002; Doyle et al. 1992; Widga and Lewis 1999).
- Three studies included information on smoking during pregnancy; the proportion ranged from 30% to 52% (Doyle et al. 1992; Gray-Donald et al. 2000; Sweeney et al. 1985).
- Body Mass Index (BMI = weight in kg/height in cm^2 x 100) was reported in three studies (Briley et al. 2002; Doyle et al. 1992; Gray-Donald et al. 2000). Mean BMI indicated acceptable weight for study participants at baseline, except in Gray-Donald et al., where mean BMI of participant women was high at 29.6–30kg/m^2.

Overall, participants in the included studies were young women with low levels of educational achievement and poor dietary intakes.

4.3.3 Characteristics of nutrition education and/or counselling interventions

All eight papers were studies of multi-faceted nutrition education interventions. It is difficult to distinguish between exclusive education and exclusive counselling interventions as there are elements of both in the strategies described in these papers.

- Information gleaned from dietary recall was used for goal setting, education and counselling in two studies (Briley et al.; Doyle et al.).
- Two were based on the same nutrition education curriculum formulated by Widga and Lewis (Briley et al. 2002; Widga and Lewis 1999). Education in these two studies included the basic concepts of nutrition, weight gain in pregnancy, breastfeeding, identification of 'harmful' substances and 'healthful' habits, along with menu planning, shopping tips and continued good nutrition after delivery. Nutrition education in two other studies included shopping, menu planning, food preparation, storage of food and improving the nutritious value of cooked food (Hunt et al.; Kafatos et al.). Written information was provided as part of the intervention for women in Greece (Kafatos et al.).
- One intervention involved computerised assessments of dietary intake based on food diaries kept by participating women, used as a basis for counselling (Doyle et al.).
- Another intervention involved counselling women to comply with a daily prescription of energy and protein, based on the woman's body weight and nutritional status (Sweeney et al.). It was designed on Higgins's model (see Higgins et al. 1989).
- A community intervention for women at risk for gestational diabetes used a nutritional advice intervention about staying within the limits of weight gain in pregnancy by avoiding energy rich and nutrient-low foods, and increasing physical activity (Gray-Donald et al.).
- Another intervention used group discussion and hands-on activities (not defined) to deliver nutrition education to adolescent mothers (Long et al. 2002).

Four interventions were delivered in the woman's home (Briley et al., Doyle et al.; Kafatos et al.; Widga and Lewis) and one at a prenatal clinic (Hunt et al.); it is not clear where the others were delivered. A dietitian, a nutritionist or a specially trained nurse delivered the intervention. The frequency of delivery was usually weekly in the first few

Table 6: Summary of studies of nutrition education interventions

Author, year	Design	Participants	Controls	Sample size	Outcome measures	Strength of evidence	Key findings
Briley et al. 2002	CT	African-American low-income women, USA	Similar	27	Maternal weight gain, MBW, pre-term birth, dietary intake	–	Babies of women in intervention group significantly heavier than control group; differences in maternal weight gain between groups not significant
Doyle et al. 1992	CT	Women attending a hospital in East London	Maternal weight 1.4kg less; BMI ~0.5 kg/m^2 less before counselling began	1082	Maternal weight gain, LBW, MBW, infant anthropometric measures, gestational age at birth	+	MBW significantly higher in counselled group; differences in LBW, head circumference, length at birth between counselled and non-counselled groups not significant; differences in maternal weight gain between counselled and non-counselled groups not significant
Gray-Donald et al. 2000	Before-after	American-Indian women from Cree communities, Canada	Similar to intervention group	219	LBW, MBW, maternal weight gain, dietary intake, physical activity, development of gestational diabetes	+	Differences in rates of LBW, BW > 4000g, MBW between groups not significant; differences in maternal weight gain between groups not significant; no differences in plasma glucose and rate of development of gestational diabetes
Hunt et al. 1976	RCT Method of randomisation not reported	Mexican women living in the USA on very low income	–	344	Dietary intakes, biochemical indices of nutritional status (deficiencies), nutrition knowledge	+	Significantly higher nutrition knowledge in intervention group; significantly higher caloric intake in intervention group; fewer women in intervention group with low RDA for calcium, vitamin C and riboflavin
Kafatos et al. 1989	RCT Cluster randomised, method not reported	Low-income women living in a remote part of northern Greece	–	559	Maternal weight gain, MBW, infant anthropometric measures, dietary intakes, gestational age, biochemical indices, infant morbidity/mortality	–	Differences in LBW, MBW, gestational age at birth between groups not significant; maternal weight gain significantly higher in intervention group
Long et al. 2002	CT	Adolescents/ high school children, USA	Details not reported	219	Maternal weight gain, MBW, LBW, Agar scores, dietary intakes, caesarean section rates, nutrition knowledge	–	Rate of LBW significantly lower in intervention group; differences in MBW, maternal weight gain between groups not significant
Sweeney et al. 1985	RCT – 'Biased coin methodology' after stratifying by pre-pregnancy weight and weight gain in first trimester	White low income women, USA	–	43	Maternal weight gain, MBW, dietary intake	–	Intervention group babies significantly heavier than control group babies; maternal weight gain higher in intervention group
Widga and Lewis 1999	CT	Low-income women, USA	More minority ethnic women than intervention group women	81	Maternal weight gain, MBW, dietary intake, gestational age at birth	–	Differences in MBW between groups not significant; significantly higher energy, folate, calcium, zinc and vitamin B6 intake in intervention women

CT = controlled trial RCT = randomised controlled trial LBW = low birth weight (< 2500g) MBW = mean birth weight weeks and then reduced to every 3 to 4 weeks until delivery. In all except one study (Kafatos et al.), which began towards the end of the first trimester, interventions began around the second or early third trimester and lasted until the end of pregnancy.

4.3.4 Outcomes measured

Seven of the eight papers measured birth weight, maternal weight gain and dietary intake of nutrients (the exception being Hunt et al. 1976). The nutrient intakes measured were energy, protein, iron, folic acid calcium, vitamins B6, B12 and vitamin C.

- Gestational age at birth was included as an outcome in Doyle et al., Kafatos et al. and Widga and Lewis.
- Kafatos et al. also collected data on infant morbidity and mortality.
- One study measured a large number of biochemical indices including haemoglobin concentrations and plasma iron (Hunt et al.).
- Another reported on rates of pregnancy complications (Sweeney et al.).
- Caesarean section rates were reported in Gray-Donald et al. and Long et al.

4.3.5 Methodological quality of nutrition education studies

There are two RCTs, one cluster randomised trial, four non-randomised CTs and one before-after study (see Table 6).

- Between 27 and 1082 participants were recruited to each of the studies.
- Most groups were comparable at baseline, except in Widga and Lewis where there were significantly more women from minority groups in the control arm.
- Only Gray-Donald et al. reported an a priori sample size calculation. The sample was powered to detect differences of 215g in mean birth weight, 1396kJ in energy intake, 0.74mmol/L in plasma glucose, 0.01kg/week increment in maternal weight and 1.9kg in weight retention at 6 weeks postpartum.
- None of the CTs reported method of group allocation.
- Blinding at outcome was not reported in any of the trials.
- The number of losses and withdrawals were reported in five trials of which two included the reasons for losses/withdrawals.
- The intention-to-treat model was not used in any of the studies.
- In the before-after study (Gray-Donald et al.) both groups were selected from the same sampling frame, although the method of sampling was not clear. Sample size was not calculated in advance.
- None of the studies provided detailed information about the timing of smoking cessation.

4.3.6 Dietary assessment methods

Six studies used 24-hour dietary recall as the chosen method of assessment at study entry and after the intervention, typically in the 36th week of pregnancy (Briley et al.; Gray-Donald et al.; Hunt et al.; Long et al.; Sweeney et al.; Widga and Lewis).

- Doyle et al. used a food diary for 1 week only in the counselled group, as a means of informing individual counselling.
- Sweeney et al. used a 7 day dietary history.

Under- or over-reporting was not considered in any of the studies.

4.3.7 Effectiveness of nutrition education interventions

See Appendix 7 for evidence of effectiveness.

Four studies measured rates of low birth weight.

- Long et al. reported a significant difference of 5.7% in favour of the intervention group ($p < 0.05$).
- Gray-Donald et al. reported rates of 2.83 and 1.94%, and Kafatos et al. 4.5 and 3.9% in the intervention and control groups respectively; these differences were not statistically significant.
- Doyle et al. reported rates of 5.4 and 7.5% low birth weight in the intervention and control groups respectively. This study did not take account of the lower rates of smoking in the intervention group.

There is indicative evidence* that nutrition counselling has no impact on rates of low birth weight.

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* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

All except one study (Hunt et al.) reported on **mean birth weight**.

- Briley et al. found a significant difference of 48g in favour of the intervention group ($p < 0.05$).
- Doyle et al. found that individual nutritional counselling provided by a dietician at home to pregnant women could have a beneficial impact on mean birth weight of their babies. The difference was 78g when adjusted for maternal body weight before study entry ($p < 0.02$). As noted earlier, the lower rates of smoking appear to have favoured the intervention group.
- Kafatos et al. and Long et al. both found differences in birth weight in favour of the intervention group but these were not significant.
- Sweeney et al. found that there were no significant differences in mean birth weight between the intervention and control groups. However, sub-group analysis of women in the 'adequate'* group and 'inadequate' group resulted in significant differences in mean birth weight in favour of the adequate group ($p < 0.04$).

Briley et al., Kafatos et al. and Sweeney et al. met few quality criteria. There is indicative evidence** from Doyle et al.'s study that nutritional counselling may have a small effect on mean birth weight.

Only one study in the review looked at *reducing* birth weight and maternal weight gain (Gray-Donald et al.); this was in a native North American group in whom gestational diabetes, macrosomia (birth weight > 4000g) and rates of caesarean section were higher than in the non-native population in the area. There is moderately strong evidence from this study that nutrition counselling and education had only a small impact on mean birth weight of babies born to mothers at risk of gestational diabetes. Babies born to women in the intervention group were 55g lighter than those in the control group, but this did not reach statistical significance. There were more babies weighing over 4000g in the intervention group but again this did not reach statistical significance. The conclusions of this study have application for groups of women who are identified as being at high risk for gestational diabetes, and consequently for having heavier babies and possibly higher rates of caesarean section.

* Ten women in the intervention group and eight in the control group had average daily intake for both protein and calories greater than 85% of the prescription – these were classed as the adequate group; 12 in the intervention group and 13 in the control group with less than 85% of calories and proteins were classed as the inadequate group.
** Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

Gestational age at birth was reported in four studies. Doyle et al., Hunt et al., Kafatos et al. and Long et al. found no significant effect on gestational age at birth. The evidence generated from Doyle et al.'s study provides moderately strong evidence that gestational age is unlikely to change as a result of nutritional counselling.

Only Kafatos et al. reported on rates of **pre-term birth**. The authors found a significant difference of 4.6% in favour of the intervention group ($p < 0.04$), but this study met few quality criteria.

Head circumference and length at birth were reported in Doyle et al. There is moderately strong evidence from this study that nutritional counselling has no significant impact on newborn **head circumference** or on length at birth.

Six studies reported on **maternal weight change**.

- Doyle et al. reported maternal weight gain of 12.3 and 11.9kg in the counselled and control groups respectively ($p = 0.221$).
- Kafatos et al. found a significant difference between intervention and control groups.
- Sweeney et al. reported significant differences in maternal weight gain between groups having adequate and inadequate diets ($p < 0.005$).
- Long et al. and Widga and Lewis found that differences between groups were not statistically significant.
- Gray-Donald et al., whose study set out to restrict weight gain during pregnancy and weight retention in the postpartum period through nutrition education and physical activity, found no significant differences in maternal weight gain between the intervention and control groups. Both groups gained over 0.5kg a week. However, those with a BMI ≥ 29kg/m^2 gained significantly less weight than those with a BMI ≤ 29 kg/m^2. It must be noted that women in native North American communities perceived that plumpness was a desirable attribute for women and that traditionally they felt that women ought to gain considerable weight during pregnancy; these issues were not addressed through the intervention.

Four of these studies, as noted earlier, met only a few quality criteria. Overall there is not enough reliable evidence about changes in maternal weight as a result of nutrition counselling and education.

Six studies measured **nutrient intakes**.

- Briley et al. reported a significant increase in iron intake ($p < 0.01$) but not in energy, calcium, or vitamin B6.
- Gray-Donald et al. found a significant reduction in caffeine intake during pregnancy in the intervention group and an increase in folate intake at 6 weeks postpartum ($p < 0.03$).
- Hunt et al. demonstrated significant increases in calories ($p < 0.02$), and calcium ($p < 0.01$), but not in protein and iron intakes.
- Kafatos et al. reported a significant increase in energy intake in the intervention group.
- Sweeney et al. found a significant increase in protein ($p < 0.01$) but not caloric intake as a result of the intervention.
- Widga and Lewis found significant increases in energy ($p < 0.05$), folate ($p < 0.01$), calcium ($p < 0.01$) and vitamin B6 intakes ($p < 0.01$) in the intervention group.

Except for Hunt et al., the studies reporting on nutrient intakes met few quality criteria.

Indices of **iron and folate** sufficiency were reported in two papers.

- Hunt et al. reported that nutrition education did not result in significant increases in haemoglobin concentration, haematocrit and serum iron. Serum folate, however, increased significantly in the intervention group ($p < 01$).
- Kafatos et al. found no significant impact on serum iron and rates of anaemia.

Two studies reported on rates of **caesarean section** (Gray-Donald et al.; Long et al.) There were no significant differences in rates reported in these studies.

Gray-Donald et al. also reported on the development of **gestational diabetes mellitus** among participants and found no differences between groups.

Gray-Donald et al. reported no differences in **breastfeeding** rates between the groups.

4.3.8 Summary of effectiveness of nutritional advice, education and counselling

This section of the review included three RCTs, four non-randomised CTs and one before-after study. Overall, variations in the characteristics of participants, study settings and quality were wide. Three met some of the quality criteria (Doyle et al.; Gray-Donald et al.; Hunt et al.) and the remaining studies met only a few.

The strength of evidence from two of the RCTs in this section is weak. The stronger evidence comes from three studies, one before-after study (Gray-Donald et al.), one CT (Doyle et al.) and one RCT (Hunt et al.).

- There is indicative evidence* that nutrition counselling can have a small impact on mean birth weight and maternal weight gain, and probably has no impact on low birth weight, gestational age at birth, and newborn head circumference and length.
- There is moderately strong evidence that nutrition education for women who are at high risk of developing gestational diabetes and delivering large babies is not effective in restricting maternal weight gain during pregnancy, reducing weight retention in the postpartum period, and preventing macrosomia and gestational diabetes mellitus.

* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

4.4 Results of evaluations of complex health and social care interventions

4.4.1 Number of studies

Two studies of complex health and social care interventions were identified, with each having at least one nutrition component. Table 7 provides a summary of the two studies. Data extraction tables are in Tables 18 and 19, Appendix 3.

4.4.2 Participants and settings

Both studies were conducted in the USA. The mean age of women participating in Graham et al.'s study was 24, with 21% below the age of 19; 38% were primiparous and 11% were married. Medicaid cover was significantly higher in the intervention group. Participants in Olds et al. were young (47% below 19), poor, primiparous and single. The adequacy of diet (average percentage of RDA of 12 nutrients) was 72.46 in the intervention group and 69.34 in the control group ($p < 0.05$). Intervention group women smoked 6.94 cigarettes a day compared with 7.65 in the control group.

4.4.3 Characteristics of the complex health and social care interventions

Both interventions were delivered in the woman's home. Peer-type home visitors were especially trained to deliver the intervention described in Graham et al. – they provided psychosocial support. Family members were encouraged to increase their support for the woman and to be present for home visits, clinic visits, maternity classes and delivery. Home visitors also made efforts to reduce family stress and act as advocates when required. Other components of the intervention were nutrition education, referral to other services such as smoking cessation, provision of information about the health risks of smoking and alcohol consumption, increased awareness of community resources, and information about prenatal care and childbirth.

In Olds et al. the key intervention was again home visits, which were designed to enhance social support in the prenatal period, increase participation in other services such as WIC and encourage healthy habits such as a good diet. Nurses made home visits about every 2 weeks – an average of nine visits for each pregnancy. Each visit lasted 1 hour and 15 minutes; more than two-thirds of

Table 7: Summary of studies of complex health and social care interventions

Author, year	Design	Participants	Controls	Sample size	Outcome measures	Strength of evidence	Key findings
Graham et al. 1992	RCT – table of random numbers used	African-American women with poor family functioning scores + one recent stressful event	–	145	LBW (< 2500g), number of visits to prenatal clinic, efficacy of screening tool	+	Differences in rates of LBW between groups not significant
Olds et al. 1986	RCT – pack of cards used to randomise participants after stratifying for race, marital status, area of residence and ethnicity	Low income, young single first-time mothers in the USA	–	400	Use of services including WIC, support-person's behaviour, obstetric conditions such as bleeding and spotting, health habits such as smoking and alcohol consumption, birth weight, length of gestation	++	Overall differences in LBW and MBW between groups not significant; significantly lower rates of pre-term delivery in intervention group smokers; significantly more women in the intervention group used nutrition supplement vouchers; significantly more women in the intervention group stopped smoking in pregnancy

RCT = randomised controlled trial LBW = low birth weight (< 2500g) the time was spent on education (including nutrition education). This intervention spanned both prenatal and postnatal periods until the child from the first pregnancy was 2 years old.

4.4.4 Outcomes measured

Low birth weight and number of prenatal care visits were the main outcomes measured in the study conducted by Graham et al. This study also tested the efficacy of a screening tool to identify women at high risk for low birth weight babies. Olds et al. also measured birth weight and the number of prenatal visits. In addition, the study provided data on the adequacy of diet, number of cigarettes smoked each day, number of services known by a participant and childbirth education attendance. The number of nutrition supplement vouchers collected (under the WIC programme), number of calls to the doctor and support-person's behaviour were also measured, and obstetric conditions such as bleeding, spotting, pregnancy-induced hypertension, oedema and kidney infections were reported.

4.4.5 Methodological quality of studies

Graham et al. recruited 145 women and Olds et al. 400 women. Graham et al.'s RCT met some of the quality criteria, including true randomisation and a priori sample size calculation. Calculations were performed to detect differences in low birth weight, but other outcomes were also studied. Groups were not comparable at baseline, there was no mention of blinding at outcome assessment and the intention-to-treat model was not used in the analysis. The method of dietary intake assessment was not reported in the paper. Olds et al. met many of the quality criteria, including true randomisation. This study did not calculate sample size beforehand and analysis was not by intention-to-treat. Dietary intake was assessed by 24 hour recall.

4.4.6 Dietary assessment methods

Olds et al. used 24 hour dietary records and recalls. Dietary data were collected for 74% of the sample for two consecutive 24 hour periods at each assessment. For an additional 14% of the sample, data were collected for only one 24 hour period. Reliability of the data was tested; the authors conclude that it was of an acceptable standard. Graham et al. did not report on dietary assessment.

4.4.7 Effectiveness of complex health and social care interventions

See Appendix 7 for evidence of effectiveness.

One of the studies (Graham et al. 1992) met some quality criteria, and the other (Olds et al. 1986) met many quality criteria, and therefore provide moderate to strong evidence of effectiveness.

Peer-type home visiting for women with low family functioning scores and recent experience of stress was found to have no impact on rates of **low birth weight** (Graham et al.). Adequacy of prenatal clinic visits did not change this outcome. It is likely that four home visits during the second and third trimesters are insufficient to address the complex social and health problems experienced by these women.

Olds et al. found that differences between intervention and control groups were not statistically significant. Sub-group analysis showed a significant difference between older non-smokers in the two groups; nurse-visited older non-smokers had a low birth weight rate of 10.7% while the controls had no low birth weight babies ($p < 0.01$). There were two low birth weights in the control group and none in the nurse-visited group among 14–16 year old mothers. However, the numbers of very young mothers were small (28 in the nurse-visited group and 17 controls), and the means cited in the table (see Appendix 3, Table 19) were not adjusted for co-variates such as gestational age. Therefore the findings need to be interpreted with caution.

Olds et al. reported on **mean birth weight**. Home visiting by trained nurses did not have a favourable impact on mean birth weight of all study participants. Sub-group analyses of babies born to very young mothers who had the benefit of nurse visits showed the babies were an average 324g heavier than their controls. When the means were adjusted for length of gestation at study entry, the effect was concentrated exclusively among adolescents registering in the programme before mid-pregnancy. As pointed out earlier, the numbers in this sub-set were small so caution is needed in interpreting this finding. There was no similar intensification of treatment effect on mean birth weight for smokers and older non-smokers after adjustment for gestational age at entry.

Gestational age at birth was not significantly different between women who were visited at home and those who were not visited (Olds et al.). However, sub-group analyses showed a statistically significant difference in favour of the control group among older non-smokers ($p < 0.01$). Differences in **preterm delivery** between all women in the intervention and control groups were not significant. But sub-group analyses showed significant differences in rates of preterm delivery in favour of the intervention group ($p < 0.05$) among smokers, and significant differences in favour of the control group among older non-smokers ($p < 0.001$). Although there were differences in rates of pre-term delivery among very young mothers, the conclusions cannot be said to be reliable because of the small numbers and absence of adjustment for co-variates.

Olds et al. also report on **maternal weight gain**. They found that differences in maternal weight gain between the groups did not reach statistical significance. Social support was enhanced as a result of the intervention and the rate of kidney infections was significantly reduced ($p < 0.01$). Differences in **obstetric complications** such as pregnancy induced hypertension and proteinurea, and obstetrical conditions such as vaginal bleeding, were not statistically significant.

Also in Olds et al., the number of **nutritional supplementation** vouchers used by the final visit was significantly higher in the intervention than in the control group ($p < 0.05$). However, this was not reflected in the adequacy of diet (percentage of RDA) between study entry and 32nd week of pregnancy. The nurse visits had a significant impact on reduction in daily **cigarette smoking** in favour of the intervention group ($p < 0.001$).

A **screening tool** used in Graham et al. to identify women nutritionally at risk of having low birth weight babies did not appear to be sensitive.

4.4.8 Summary of effectiveness of complex health and social care interventions

There is strong evidence that complex health and social care interventions designed to improve nutritional intake and social support among low-income pregnant women, and delivered in their homes, are very likely to have no impact on low birth weight, mean birth weight and gestational age at birth; and are likely to have a small but significant impact on reduction in the number of cigarettes smoked each day, and rates of preterm birth in favour of smokers in the intervention group. Although there is not enough detail in the papers to make an assessment of nutrition education input, these studies provide important evidence to inform the development of complex health and social care interventions incorporating elements of food support.

4.5 Economic studies of food-support programmes

This section stands apart from the four previous sections in that inclusion/exclusion criteria, data handling and method of analysis are different. All economic studies and any study design were accepted, including retrospective analyses of data; this was necessary because almost all economic studies are based on retrospective data linkage studies. Cost studies of vitamin supplementation are excluded. One reviewer appraised and reviewed all studies included in this section.

4.5.1 Number of studies

A total of 12 economic papers were identified in the search. Of these, eight are studies of WIC, three of EFNEP and one examined breastfeeding. One paper reported on a meta-analysis of costing studies of WIC. These studies are summarised in Tables 8-10. Full economic appraisal of each of the included studies detailed in these tables is given in Appendix 5.

4.5.2 Quality of economic studies

All papers from the USA used charges, reimbursement or some variant of this, rather than actual treatment costs. While often claiming to be cost-benefit studies, there was no measurement of benefit beyond averted treatment costs, so they were generally cost-consequence studies. None of these studies was based on an RCT; they compared WIC or EFNEP participants with eligible non-participants, so selection bias is likely. Although WIC led to an increase in prenatal care, these costs were generally not included. There was limited or no sensitivity analyses.

4.5.3 Summary of economic studies

Little can be said with confidence about the cost effectiveness of WIC or EFNEP due to the poor quality of studies and the strength of the designs.

Table 8: Summary of WIC studies of cost

Author, year, country	Study type, no. participants	Outcomes	Costs	Comments
Schramm 1985, USA	Record linkage WIC 1883 Non-WIC 5745	**LBW %** WIC 10.7 Non-WIC 12.6	**Mothers** No differences **Babies (up to 30 days)** Medicaid costs WIC $574 Non-WIC $672 **WIC costs** $229,000 **Medicaid savings** $191,000 CBR 1:0.83 (95% CI 0.4–1.3)	Limited testing of comparability; problems with matching; no sensitivity analyses
Schramm 1986, USA	Record linkage WIC 3261 Non-WIC 5285	**LBW %** WIC 10.1 Non-WIC 13.1 **NICU admissions** WIC 3.9% Non-WIC 4.5%	**Babies (up to 45 days)** Medicaid costs WIC $1250 Non-WIC $1326 **WIC costs** $508,000 **CBR** 1:0.49 (95% CI 0.07–0.9)	As above

LBW = low birth weight (< 2500g) MBW = mean birth weight CBR = cost benefit ratio (benefit here refers to averted costs)

Table 8: Summary of WIC studies of cost (cont.)

Author, year, country	Study type, no. participants	Outcomes	Costs	Comments
Joyce et al. 1988 USA	Statistical modelling study	Estimated lives saved per 1000 additional participants (neonatal mortality reductions) WIC White 1.2–3.7 Black 3.1–6.9 Estimated LBW births averted per 1000 additional participants WIC White 0–30.5 Black 23.1–53.3	Estimated cost per additional 1000 participants (neonatal mortality) (at 1984 values) WIC White $145,000 Black $145,000 Estimated cost per life saved (at 1984 values) WIC White $39–118 Black $21–47 Estimated cost per additional 1000 participants to avert LBW (at 1984 values) WIC White $4.7–not stated Black $2.6–6.3	Inputs to equations rather crude; assumption that additional users will be same as current users; no sensitivity analyses
Devaney et al. 1990, 1992; Devaney 1998 USA	Record linkage 105,000 births	Estimated reduction in rates of LBW 2.2–5.1% Estimated reduction in rates of pre-term births 2.3–6.3%	Savings in Medicaid costs for mothers and newborns (0–60 days) WIC mothers and babies $277–598 Estimated WIC programme cost for newborns and mothers $151–232 CBR for mothers and newborns $1.77–3.13 CBR for babies only $2.84–3.90	Limited information on comparability of cases deleted from linkage and comparability of WIC non-WIC; no sensitivity analyses
Buescher et al. 1993 USA	Record linkage 22,343 women	Estimated reduction in LBW White 22% Black 31% Estimated reduction in VLBW White 44% Black 57%	Actual claims (up to 60 days) WIC $1856 Non-WIC $2350 WIC programme costs $170 per person CBR White 1:1.92 Black 1:3.75	Cost differences over-estimated due to treatment costs spanning 60 days; no sensitivity analyses
Avruch and Cackley 1995 USA	Review – economic modelling Included studies ranged from 49 to 31,732 women	Reported reductions in LBW 0.9–5.2 percentage points Reported reduction in VLBW 0.3–1.8 percentage points	Estimated total 1st year medical costs VLBW $56,407 MLBW $9937	Some of costing quite crude; no sensitivity analyses

LBW = low birth weight (< 2500g) MLBW = moderately low birth weight VLBW = very low birth weight CBR = cost benefit ratio (benefit here refers to averted costs)

Table 9: Summary of EFNEP studies of cost

Author, year, country	Study type, no. participants	Outcomes	Costs	Comments
Burney and Haughton 2002 USA	Observational 384 women	Participants saved $124–234 a year and ate more fruit and vegetables	Cost of programme $388/person Savings on food per month, mean $ [SD] A 10.36 [9.79] B 19.53 [6.79] C –5.52 [8.64] Savings accrued for 5 years at 3% discount $696 at 7% discount $147 savings	Consecutive allocation to A, B and C; long-term effectiveness of intervention doubtful; food recall may be biased; limited sensitivity analyses
Rajgopal et al. 2002 USA	Modelling based on literature 3100 women in Virginia EFNEP	Reduction in diseases and conditions through 'optimal nutrition behaviour'	Cost of programme $1,713,081 Averted costs of treatment $17,880,626 Averted costs of lost productivity $343,354 CBR 1:10.64 Sensitivity analyses CBR range 1:2.66-17.04	24 hour food recall may be biased; assumption that EFNEP graduates practice optimal nutrition behaviour for life; averted costs of lost productivity assume that women are employed; limited sensitivity analysis; costs of LBW only modelled to 1 year
Schuster et al. 2003 USA	Modelling based on literature 368 women in Oregon EFNEP	Reduction in diseases and conditions through 'optimal nutrition behaviour'	Cost of Oregon programme $446,003 Averted costs of time off work (treatment + lost productivity) $1,619,321 CBR 1:3.63 CBR range 1:0.91-1.94.	As above - slightly better sensitivity analysis

CBR = cost benefit ratio (benefit here refers to averted costs)

Table 10: Breastfeeding study

Author, year, country	Study type, no. participants	Outcomes	Costs	Comments
Tuttle and Dewey 1996 USA	Modelling study of effects of exclusive breastfeeding	Interval between pregnancies, gastro-intestinal infection, otitis media	Cost savings WIC over 90 months With rebate $202 Without rebate $1787	No sensitivity analyses except discount rates

5 Discussion and conclusions

As far as the authors are aware, this is the first systematic review of food-support interventions for childbearing women in developed country settings. Rigorous systematic review methods were used throughout the work. An information officer at the Centre for Reviews and Dissemination (CRD) developed the search strategy and conducted the search; researchers and reviewers were involved in the review process and analysis; an experienced researcher and reviewer supervised the review process at every stage; and a perinatal health economist conducted analysis of the economic studies of national programmes.

The entire process was transparent, with two reviewers independently involved in the different stages: trawling, short-listing of papers, assessment of quality of studies and production of tables. The draft report was peer reviewed by seven academics with expertise and interest in public health, public policy, nutrition, perinatal health, and maternal and child health.

This section starts with a description of the limitations of the review. This is followed by a discussion of the effectiveness of strategies for improving nutrition among childbearing women, with a note on whether or not food-support programmes, as reported in included studies, address the problem of inequalities in the health of childbearing women. The methodological quality of studies is discussed, including examination of some studies excluded from this review. Gaps in the evidence are identified, and implications for policy, practice and research are described.

5.1 Limitations and challenges of the review

This review included RCTs, non-randomised controlled trials and before-after studies. The exclusion of other study designs may have resulted in a loss of studies reporting on process, views and costs. As it stands there is little information on women's views, costs or process outcomes that may have been useful in informing the development of current practice. These design limitations also resulted in exclusion of studies of very marginalised groups such as travellers and homeless women. Unpublished studies were not sought owing to time constraints.

This search string was used throughout the strategy to limit the various sub-sections of the search:

> *mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum*

Therefore studies not using these descriptors were not identified.

The strategy for this review was to include all studies identified in the search that met the review criteria. Quality assessment was conducted only after inclusion. It was found that many of the included studies were flawed, with problems noted either in the design or in the analysis. Conclusions from these studies are considered likely or very likely to alter and do not therefore provide reliable evidence of effectiveness. This has been noted throughout the review.

A priori sample size was calculated for only three studies (Graham et al. 1992; Rush et al. 1980, 1988) These studies were powered to detect differences in key perinatal outcomes – low birth weight, mean birth weight and gestational age at birth. Findings from studies not powered for a particular outcome were considered in this context.

There was marked heterogeneity in the participants with respect to age, ethnicity and anthropometric measurements. In some papers these were not described, or if described they were not factored into the analysis. Even the start and duration of the intervention with respect to timing in gestation varied a great deal across included studies. The variability in studies has made it difficult to review them all together and to draw out straightforward conclusions about their effectiveness. Furthermore, variability in compliance with food supplements in the WIC studies makes it difficult to compare them with the nutrition education interventions in terms of outcomes.

5.2 Applicability of review findings to the UK population

This review was commissioned to inform policy and practice in the UK. The majority of included studies (all except four) were set in North America.

Between-country differences in healthcare, social care, population characteristics, food fortification and welfare provision limit the usefulness of these review findings. Findings from the WIC studies, which demonstrate many positive effects, need to be interpreted with caution.

5.3 Evidence of effectiveness of food-support programmes

The effectiveness of food-support strategies is discussed here in the light of the quality rating of included studies. Evidence described in this section is based on findings of only those studies that meet some or all of the quality criteria for this review. Those studies meeting only a few or none of the criteria cannot be relied on as a source of evidence. Furthermore, less weight is given to negative conclusions on outcomes for which the study was not powered. Readers are referred to sections 4.1.7, 4.2.7, 4.3.6 and 4.4.6 for a more extensive discussion of findings from all included studies. See Appendix 7 for evidence of effectiveness.

Evidence of effectiveness of food support on **low birth weight** is generated from seven studies that meet some or many quality criteria for the review:

- two WIC evaluations (Metcoff et al. 1985; Rush et al. 1988)
- one stand-alone nutrition supplement intervention (Rush et al. 1980)
- two nutrition counselling/education studies (Doyle et al. 1992; Gray-Donald et al. 2000)
- two complex health and social care intervention studies (Graham et al. 1992; Olds et al. 1986).

None of the studies found a significant favourable impact on low birth weight in the intervention group. A point worth noting is that one of the large-scale studies (Rush et al. 1988, the second WIC national evaluation) recruited a smaller sample of women than was originally planned; the study therefore did not have enough power to detect expected changes in low birth weight. Whether a larger sample size would have found a significant reduction in low birth weight is debatable.

We can have confidence from these studies that multi-faceted food-support programmes such as WIC, stand-alone nutrition supplement programmes, nutrition counselling and education, or complex health and social care interventions that include a nutrition education component are unlikely to have an impact on rates of low birth weight in a woman's first pregnancy. Further research is needed to investigate the impact of such programmes on rates of low birth weight in future pregnancies. Low birth weight is probably not a useful measure of the short-term effectiveness of such programmes.

Evidence of the effectiveness of food support on **mean birth weight** is generated from six included studies that met some or many quality criteria for the review:

- two WIC evaluation studies (Metcoff et al. 1985; Rush et al. 1988)
- one stand-alone nutrition supplement intervention (Rush et al. 1980)
- two nutrition counselling/education studies (Doyle et al. 1992; Gray-Donald et al. 2000)
- one complex health and social care intervention study (Olds et al. 1986).

The 1988 national WIC evaluation and one smaller study found that there was no significant impact of WIC participation on mean birth weight of the whole sample. One of these studies (Metcoff et al.), found a statistically significant difference of 175g among babies born to heavy smokers (> 10 cigarettes/day) participating in WIC ($p < 0.017$).

Findings from a study of stand-alone nutrition supplements adds strength to the evidence that babies born to smokers may benefit from food-support programmes (Rush et al. 1980). One study of nutrition counselling delivered by a nutritionist to women in the home setting during the second and third trimesters provides indicative evidence* of a favourable impact on mean birth weight (Doyle et al.). A complex health and social care intervention with nutrition advice as one of several components delivered during a home visit had no favourable impact on mean birth weight except among babies born to very young mothers (Olds et al.).

There is indicative evidence* from included studies that food-support programmes may have a favourable effect on mean birth weight in high-risk sub-groups such as heavy smokers and very young mothers. None of the studies measured the effectiveness of the programmes on mean birth weight in later pregnancies.

One study comprising nutrition education and physical activity, targeting overweight pregnant women from native-American Cree communities in Canada, aimed to reduce the incidence of gestational diabetes and consequently **macrosomia** (> 4kg birth weight) (Gray-Donald et al.). This intervention had no substantial effect on birth weight. However, the study remains important because of the higher proportion of overweight women in social class V in the UK (Department of Health 1999a) and the associated risk of gestational diabetes. Stand-alone energy restriction during pregnancy is not recommended because of the danger of low birth weight.

Three studies that met some or many quality criteria provide evidence of effectiveness of **pre-term birth**:

- one WIC evaluation (Rush et al. 1988)
- one stand-alone nutrition supplemental intervention (Rush et al. 1980)
- one complex health and social care intervention study (Olds et al. 1986).

* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

Rush et al. (1988) found no significant differences in rates of pre-term birth. There is strong evidence that high protein supplements result in very early pre-term births in Rush et al. (1980). Olds et al. found that preterm birth rates were lower among smokers in the intervention group. There is moderately strong evidence that a complex health and social care intervention incorporating nutrition education/counselling can result in lower rates of pre-term birth among participants who smoke during pregnancy.

There is strong evidence that *high protein* supplements taken during pregnancy by women who have adequate protein intakes at baseline is very likely to result in **intrauterine growth retardation** (Rush et al. 1980).

Evidence of the effectiveness for changes in **duration of gestation** come from five studies that met some or many quality criteria:

- one WIC evaluation (Rush et al. 1988)
- one stand-alone nutrition intervention (Viegas et al. 1982b)
- two nutrition education/counselling interventions (Doyle et al. 1992; Gray-Donald et al. 2000)
- one complex health and social care intervention (Olds et al. 1986)

None of the studies found significant differences in duration of gestation between intervention and control groups. There is moderately strong evidence that WIC participation, nutrition supplementation and nutrition education interventions have no significant effect on duration of gestation.

Head circumference, an indicator of fetal growth, was reported in three studies meeting some or many quality criteria:

- one WIC evaluation (Rush et al. 1988)
- one stand-alone nutrition intervention (Rush et al. 1980)
- one nutrition counselling intervention (Doyle et al. 1992).

Neither the nutrition counselling intervention nor the stand-alone nutrition supplement had a significant impact on head circumference. However, Rush et al. (1988) reported a small but statistically significant increase in head circumference that was independent of birth weight. Even so, it can be confidently said that programmes such as WIC can have a beneficial effect on newborn head circumference. While this in itself is a good outcome, it will be useful to study the effects over time, as this was an incidental finding. Future studies of food support might include head circumference as an additional outcome of interest.

Programme quality was reported in Rush et al. (1988), the second national WIC evaluation. This study found that higher programme quality had beneficial effects on rates of low birth weight and newborn head circumference. Head circumference varied less than low birth weight with programme quality, suggesting that it might have been more directly related to food supplementation. It is notable that WIC directors assessed programme quality, so there may have been an element of subjectivity in the assessments.

Furthermore, there is not sufficient evidence from this study on which components of the programme (counselling, quality of nutrition education, individual care plans, or compliance with state and federal regulations) resulted in these associations. This study provides indicative evidence* that improvements in programme quality may have a positive effect on low birth weight.

Maternal weight gain, an intermediate outcome for birth weight, was reported in six studies meeting some or many quality criteria:

- two WIC evaluations (Metcoff et al. 1985; Rush et al. 1988)
- one stand-alone supplement nutrition intervention study (Rush et al. 1980)
- two counselling intervention studies (Doyle et al. 1992; Gray-Donald et al. 2000)
- one complex health and social care intervention (Olds et al. 1986).

It is notable that only one study was powered to detect a change in maternal weight (Gray-Donald et al.). The large-scale national WIC evaluation (Rush et al. 1988) found that women in the WIC group were lighter than the controls at entry to the programme, but by the end of their pregnancy their weights were the same as the control group. A proportion of control group women who crossed over to WIC later on showed increases in weight by the end of the study.

* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

Metcoff et al.'s RCT found that WIC women weighed 2.5kg more at 36 weeks than control group women ($p = 0.57$), after adjusting for differences in weight at entry to the study (19 weeks).

The stand-alone protein-energy supplement, ie the high-protein arm of the study, was effective in increasing weight in early pregnancy ($p < 0.05$) (Rush et al. 1980). A sub-group of women in the high-protein group who delivered their babies before term went on to lose their advantage and by delivery they had markedly decreased weight gain compared with the balanced energy-protein group and controls. The concomitant negative impact on fetal growth in this group reduces the usefulness of its effect on early pregnancy weight gain.

Doyle et al. found a difference of 0.4kg in maternal weight gain as a result of nutrition counselling only ($p = 0.221$).

The complex health and social care intervention reported differences in maternal weight gain but these were not significant (Olds et al.).

Gray-Donald et al. set out to restrict maternal weight gain in pregnancy and reduce weight retention in the postpartum period, and found that the nutrition education intervention had no significant impact on weight restriction during pregnancy either among women with BMI $\geq 29 kg/m^2$ or $< 29 kg/m^2$.

There is evidence that programmes such as WIC are effective in increasing weight gain among women who are at risk as a consequence of poor pre-pregnancy weight or poor weight gain in early pregnancy. It has been suggested that food support in the interpregnancy interval may be effective in improving perinatal outcomes in subsequent pregnancies.

Maternal nutrient intake was measured in seven studies meeting some or many quality criteria:

- three evaluations of WIC (Metcoff et al. 1985; Pehrsson et al. 2001; Rush et al. 1988)
- two nutrition education intervention studies (Gray-Donald et al. 2000; Hunt et al.1976)
- two studies of complex health and social care interventions (Graham et al. 1992; Olds et al. 1986).

None of these studies were powered to detect differences in nutrient intake.

Metcoff et al. found that differences in intakes of energy and protein were not significant. This study did not find a significant difference between groups in maternal weight gain.

Rush et al. (1988) found that WIC participation resulted in significant increases in intakes of energy, protein, vitamin B6, iron, thiamin, riboflavin, vitamin C and calcium. Energy intake was below 100% RDA for both control and intervention group women. Maternal weight gain reflected increases in energy intake.

Pehrsson et al. studied dietary intakes of iron only and found that this did not differ between groups.

The stand-alone nutrition supplement study (Rush et al. 1980) reports the high-protein supplemented group taking 326 calories a day from the beverage; this was 80% over the reported intake in the control group. So 20% of calories could be considered as substituting for calories that would otherwise be taken in the regular diet. The second intervention group, who received a balanced protein-energy supplement, reported taking 98% of calories from the beverage. Mean caloric intake for the control group was low. The reported mean intake for protein was 101.9g/day; this meant that the supplements achieved the intended level for the study.

The before-after study of a nutrition education intervention to restrict weight gain during pregnancy (Gray-Donald et al.) found that energy intakes during pregnancy were high, at approximately 140kJ/kg; this was higher than that recommended for overweight women. There were no differences in dietary intake between the intervention and control groups except for a reduction in caffeine in the intervention group. A significant difference was noted in folate intake at 6 weeks postpartum.

A non-randomised CT of a nutrition education intervention (Hunt et al 1976.) found significant differences between groups in calcium, protein, carbohydrate, vitamin C, niacin, riboflavin and thiamin intake but not iron or fat intake. A significant improvement was seen in the proportion of intervention group women with low RDA of calcium, ascorbic acid and riboflavin.

Olds et al. reported greater improvement in the quality of women's diets as a result of the intervention; the effect was greatest among smokers ($p < 0.04$). There were no differences between groups in the adequacy of diet (measured as percentage of RDA). There is evidence from this review that food and nutrition supplements, and nutrition education can increase intakes of a wide variety of nutrients. Interventions need to be tailored to address deficiencies in the target population.

Two studies meeting some of the quality criteria looked at rates of smoking:

- one WIC evaluation (Rush et al. 1988)
- one complex health and social care intervention (Olds et al. 1986).

Rush et al. found that significantly more WIC women than controls were smoking at study entry ($p < 0.05$), but by the end of the programme WIC women were smoking more than the controls. It must be noted that at the time this study was conducted, smoking cessation was not a stated part of the programme.

The health-visiting intervention (Olds et al.) demonstrated a significant reduction in the number of cigarettes smoked by women in the intervention group ($p < 0.0001$).

Breastfeeding was reported in two studies:

- one WIC evaluation (Rush et al. 1988)
- one nutrition education intervention (Gray-Donald et al. 2000).

There is little evidence of whether or not WIC participation affected the rate of breastfeeding at hospital discharge (Rush et al. 1988). Reviews of studies (not included in this review) conducted after breastfeeding promotion became an integral part of the WIC programme provide more positive evidence (Fairbank et al. 2000; Renfrew et al. 2005).

Gray-Donald et al. reported that breastfeeding initiation was high in both groups but there were no significant differences between them. Breastfeeding rates were reported to be high overall in native-American Cree communities.

Pregnancy and obstetric complications were reported in just one higher quality study – the WIC evaluation (Rush et al. 1988). There is moderately strong evidence from this study that participation in programmes such as WIC may result in a lower rate of premature rupture of membranes. Additionally, there is reliable evidence that

WIC has no demonstrable impact on maternal conditions such as hypertension, haemorrhage, infections, and cephalopelvic disproportion.

Haematological and biochemical indices of iron and folate sufficiency were reported in two WIC studies (Pehrsson et al. 2001; Rush et al. 1988) and one nutrition education study (Hunt et al. 1976). There is evidence from these studies that prenatal WIC participation has no significant impact on haemoglobin concentration, and continuous postpartum participation results in significant increases in haemoglobin concentration and lower levels of anaemia. Hunt et al. provides indicative evidence* that nutrition education may result in increases in serum folacin but not in serum iron, RBC folacin or haematocrit.

Nutrition counselling is delivered as part of WIC. It is notable that there is no compulsion for a woman to attend the two sessions offered at entry to the programme. The 1988 WIC evaluation found that significantly fewer women in the WIC programme compared to the control group had no nutrition counselling during pregnancy; and more WIC women had more than three sessions (Rush et al. 1988).

Only one included study investigated the effect of the intervention on increased **participation in a food-support programme** (Graham et al. 1992). This study provides good evidence that when interventions are delivered together, one can enhance the effectiveness of the others. This complex health and social care intervention involving home visits throughout pregnancy demonstrated a significant increase in the collection of food-support vouchers.

Three studies had some information on **women's views**. Rush et al. (1988) found that 66% of WIC women and 61% of control group women had changed their eating habits as a result of receiving nutrition education. The method of individualised feedback on computerised forms was welcomed by participants in one nutrition counselling study (Doyle et al. 1992). Native-American women participating in an intervention to prevent gestational diabetes provided plausible explanations about why the outcomes were not achieved (Gray-Donald et al. 2000).

* Indicative evidence – findings from the included studies which are plausible (and positive) but there may be problems with the methodology. More research is needed to confirm these findings.

5.4 A note on if and how food-support programmes address the problem of health inequalities

This review attempts to explore the potential of food-support programmes to reduce health inequalities. With reference to the key indicators, it does not provide strong enough evidence to support the premise that food support has an impact on health status indicators of babies born to low-income and socially disadvantaged women. No significant impact was observed on rates of low birth weight. There is some evidence to suggest that WIC participation may positively influence birth weights of babies born to smokers (Metcoff et al. 1985). The RCT of a stand-alone protein-energy supplementation provides further support for this finding (Rush et al. 1980).

In the UK it is recognised that smoking in pregnancy is more prevalent among women in low socio-economic groups than among affluent educated women (Hamlyn et al. 2002; Penn and Owen 2002). From these studies it can be inferred that programmes incorporating food supplements may have some, although limited, potential to reduce health inequalities. Furthermore, there may be even greater potential for reductions in low birth weight if multifaceted food-support programmes are designed also to support smoking cessation during pregnancy.

Beyond the subject of key indicators, there is evidence that programmes incorporating food supplementation, such as WIC, are likely to improve dietary intakes, maternal weight gain, and haematological and biochemical indices; and that nutrition education interventions may improve both dietary intake and mean birth weight among participating women. Findings from the Avon longitudinal study, ALSPAC (Rogers and Emmet 1998), the Southampton Women's Study (see the SWS site at the MRC Environmental Epidemiology Unit, www.mrc.soton.ac.uk) and other smaller studies in the UK (Ford 2004) have shown that nutrient intake during pregnancy is poorer among low-income and socially disadvantaged women. Poverty may act as a barrier to accessing a healthy diet during this critical time.

This review clearly demonstrates that food-support programmes that offer a substantial quantity of food along with nutrition education (for example WIC) can improve nutrient intakes among poor women. WIC studies provide unequivocal evidence of increases in iron, protein, calcium and Vitamin C (Rush et al. 1988).

Maternal weight gain is also favourably affected by participation in WIC, with more benefits seen among women who enter the programme early in their pregnancy (Metcoff et al. 1985; Rush et al. 1988). Other likely benefits are increases in serum iron and haemoglobin, and reduction in anaemia with postpartum participation in WIC (Pehrsson et al. 2001). Results from the better quality studies of nutrition education interventions strengthen the evidence base on dietary intake (Doyle et al. 1992).

It is likely that studies examining only immediate outcomes related to food-support programmes are limited in their potential. They do not capture the long-term impact of such interventions, in particular the impact on later births to women who received food support. Epidemiological studies of the Dutch Hunger Winter of 1944 suggest long-term biological effects of maternal under-nutrition even into the next generation (Lumey and Stein 1997). It is possible that the reverse is true, that improved nutrition has long-term biological impacts. Improvements in maternal health and nutrition may, over time, result in improvements to the health of subsequent babies. It is unlikely that short-term food support offered to low-income and socially disadvantaged childbearing women will be sufficient to address inequalities in health; a life-course approach is probably more likely to have better health outcomes for mothers and their babies. Food-support programmes in pregnancy might be seen as the first phase in such an approach.

There is a need for further study to develop the evidence base on food-support programmes and health inequalities.

5.5 Methodological quality and design of studies evaluating food-support programmes

There are other evaluation studies of food-support programmes identified through the search that are not included in this review, mostly evaluations of WIC and EFNEP (see Excluded studies, Appendix 6). Several have been influential in directing public health policy and federal investment in the USA – they have received a great deal of attention from academics and policy-makers, and have been cited repeatedly in the literature. Cost estimates of programmes were made on the basis of some of these studies – by calculating federal government savings made by avoiding the costs of treatment for low birth weight babies in the first year of life. It is useful to discuss concerns about these excluded studies.

The first major difficulty is the design of the studies. Many of the excluded WIC and EFNEP evaluations identified in the search were not conducted prospectively – they were, for example, retrospective analyses of WIC, birth/death and Medicaid records. Participant records were matched with vital statistics and WIC records of controls, often after the intervention came to an end (ie at the end of the pregnancy), and in some cases after a gap of a few years. The problem of matching was addressed in some studies by using the fixed-effect modelling method. These studies used sibling pairs discordant for their mother's participation in the programme.

However, the data were collected retrospectively. Mothers participated in WIC for the first or the second sibling, or there were other births to the mother between the two siblings whose data were used in the study. These problems weakened the design of the studies to an extent that including them in this review could have led to unreliable conclusions. Besharov and Germanis (2000) reviewed WIC studies and found three key problems with these evaluations: selection bias, simultaneity bias and lack of generalisability.

Other recent reviews of the WIC programme include studies that are excluded from this review on the basis of design and/or participant selection, and therefore came to different headline conclusions. Owen and Owen (1997), for example, included five studies (Caan et al. 1987; Kennedy et al. 1982; Rush et al. 1988;* Schramm 1985; Stockbauer 1987) that are excluded from this review on methodological grounds; they found a lower rate of low birth weight in babies born to WIC participants.

Food such as that provided in the WIC programme is used to supplement household food. So the food basket given to a woman may be spread out among a number of family members, with the woman herself getting some, all or none of it. Therefore, assessment of dietary intake for the individual woman in question is an important part of these studies. Different methods were used to assess dietary intake in the studies included in this review, and different databases were employed to compute the nutrient content of these diets. Studies variously used 24 hour dietary recall (most common), 7 day dietary histories, or food diaries.

*** This is not Rush et al. (1988) in section 4.1. See Appendix 6 for excluded studies.**

These methods have their strengths and weaknesses. The most robust method among the included studies was used in the second national WIC evaluation (Rush et al. 1988) – the authors used 24 hour recall for collecting data on dietary intake at study entry and 36 weeks, and analysed these data with the help of the USDA National Nutrient Database (USDA National Nutrient Database for Standard Reference – reputedly the most comprehensive of such databases – available at www.ars.usda.gov), with additional information taken from food manufacturers and other nutrient databases as and when required. Two studies used food processor software and one used the Canadian Nutrient Files database as well (Briley et al. 2002; Gray-Donald et al. 2000). The study set in Greece (Kafatos et al. 1989) was conducted with the support of the Institute of Medicine, USA.

Differences in approach to the assessment of nutrient intake (24 hour recall, food frequency questionnaires and food diaries) make the comparison of outcomes of studies aiming to change dietary intake difficult. A recent report of a study examining methods of dietary assessment in low-income households suggests that 24 hour dietary recall provides measures that are consistent (physiologically) with levels of intake commensurate with growth (Nelson et al. 2003). It also appears to be the most discriminating method in relation to other measures such as weight change and health. This study found that 24 hour recall was least likely to generate mis-reporting of diet, although issues regarding low-energy reporting and overweight still remained.

It is well known that under-reporting of energy is a common problem in studies of nutrient intake (Rogers and Emmet 1998). Only one study took account of under-reporting (Rush et al. 1988).

5.6 Gaps in the evidence underpinning the need for food support in the UK

If the key aim of food-support programmes is to improve rates of low birth weight and increase mean birth weight among low-income groups in the UK, then the epidemiological evidence base linking maternal nutrition to low birth weight needs to be strengthened. The Dutch Hunger Winter studies have shown that even under famine conditions, birth size and body proportions may vary only with third trimester maternal starvation (Stein et al. 1995).

Existing evidence linking maternal nutrition and birth weight from studies conducted in the UK is inconclusive. Overall, Cochrane reviews of the impact of nutritional supplements during pregnancy on key perinatal outcomes do not provide evidence of a favourable effect of any macro- or micro-nutrient supplementation on key pregnancy outcomes (see Appendix 8). Moreover, they include studies from both developed and developing countries. The only nutrient that has been shown to prevent adverse pregnancy outcomes is folic acid, but this is with reference to periconceptional supplementation and the prevention of neural tube defects (Barker 1990). As discussed earlier there is a need to generate evidence on the effect of food support on subsequent pregnancies.

However, public health nutrition interventions might have aims and objectives that go beyond the improvement of immediate pregnancy outcomes. They could address the need for improvement of physical and psychological health of the infant, child and adult, and improvement in the health and wellbeing of childbearing women. The volume of observational studies linking fetal nutrition to adult health is growing since the work of Barker was first published (Hollier 2005). This may provide the basis for long-term health gains. The Southampton Women's Study (SWS) will provide more information about the links between pre-pregnancy nutritional status, nutrition during pregnancy and birth outcomes (see the SWS site at the MRC Environmental Epidemiology Unit, www.mrc.soton.ac.uk).

There is little evidence in the literature that improvement in nutritional intake reduces maternal mortality and serious maternal morbidity in industrialised countries.
Poor nutrition has not been identified as a cause of maternal mortality and serious maternal morbidity in the UK, unlike in developing countries where there are clear links between poor nutritional status and maternal mortality and serious morbidity. However, beyond the realm of serious morbidities lies the yet unexplored area of non-life threatening maternal morbidity related to maternal nutrition that might have a less conspicuous impact on wellbeing and loss of productivity in women's lives.

Cochrane reviews (see Appendix 8) provide evidence that nutrition supplementation may have benefits for the mother. For example, iron supplementation during pregnancy prevents low haemoglobin concentrations at delivery and 6 months postpartum (Mahomed 1999). Like other Cochrane reviews it is based on studies from both developed and developing countries. Anecdotal reports of tiredness and exhaustion during pregnancy and early motherhood appear common, although scientific evidence to support the link between nutrition and these symptoms does not exist and needs to be explored. Studies demonstrating that normal physiological adaptation during pregnancy prevents the occurrence of adverse pregnancy outcomes even with severe reductions in nutrient intake have not taken account of women's perceptions of their own health. There is a dearth of studies investigating the impact of nutrition on women's health in the short and long term. Good quality studies need to be conducted, both qualitative and quantitative, to find out to what extent poor nutrition leads to other maternal morbidities such as maternal exhaustion and tiredness, postnatal depression, and longer-term consequences on the health of childbearing women.

Not enough information is available about maternal nutrient intake and dietary deficiencies among childbearing women in the UK, although the Southampton Women’s Study is likely to give far more information than has previously been available. From the little evidence that is available, key nutrients such as iron, folate and energy appear to be lacking in the diets of women. More information is needed, particularly about the diets of low-income and socially disadvantaged women in the UK, both before and during pregnancy. It will be useful to know the extent of nutrient deficiencies among teenage mothers and women from minority ethnic groups. Another group for which there is little evidence is women who are overweight. More investigation is needed on how financial constraints may impact on dietary intake in sub-groups of women who may or may not be eligible for income support and other welfare benefits. Further:

- most interventions studied began in the late first or the second trimester
- none of the studies of interventions targeting women in the inter-pregnancy interval met the inclusion criteria for this review
- more work is needed on interventions beginning in the periconceptional period or earlier
- no studies examined the existing Welfare Food Scheme (UK).

Additionally there is a need to investigate the impact of food-support programmes for low-income women on nutrition awareness and nutritional status among other family members.

5.7 Implications for policy and practice

The diets of low-income and socially disadvantaged women and their families in developed countries such as the UK and USA are relatively poor. This review demonstrates that food-support programmes such as WIC can have a significant impact on the nutrient intake of participating women and their families. It is therefore important to provide food (among other support) to low-income childbearing women and their families.

A clear set of aims and objectives for food-support programmes for childbearing women needs to be developed in the light of existing evidence of need in the population, and the findings from this and other reviews. The outcomes used to measure the success of such programmes need careful consideration. Low birth weight in a first pregnancy should not be considered as the key measure of success of food support for poor women. It is probably more useful to use low birth weight as a key indicator when food support is provided in addition to smoking cessation, the only intervention so far known to have a favourable impact on low birth weight.

The addition of other anthropometric measurements such as head circumference at birth, in addition to mean birth weight, may prove to be a useful strategy. Including pre-term birth as a headline indicator for food-support programmes is probably not useful as there is as yet no clinical evidence linking pre-term birth and maternal nutrition. Recent reviews of pre-term birth have concluded that there are currently no effective preventive interventions (Bibby and Stewart 2004; Hollier 2005). Furthermore there is no strong existing evidence of links between the patho-physiological processes of pre-term birth and the patterns of social differences in their occurrence (Lumley 2003). Pre-term babies account for a significant number of low birth weight babies in the UK. It would be inadvisable to think that one way of reducing low birth weight would be to reduce the incidence of pre-term births.

Screening tools for use in community settings need to be developed for the detection of women at risk of poor pregnancy outcomes to make optimal use of resources and to achieve greater programme success. These screening tools will need to take account of maternal anthropometric measurements, previous history of low birth weight, detailed information about smoking before and during pregnancy, and ethnicity. Food-support programmes are likely to work better if they are part of a multi-faceted intervention.

This has implications in the UK for the way the Welfare Food Scheme (and its successor Healthy Start) and Sure Start are implemented. All at-risk women, but especially those who smoke heavily, and very young mothers will benefit from being reached early in their pregnancy. Improvement in inter-pregnancy nutrition and periconceptional nutritional status is likely to benefit all women, particularly those at risk of poor pregnancy outcomes.

High-protein supplements should not be part of any programme for childbearing women. Food programmes should aim to achieve 100% RDA of calories, as energy brings with it several other important nutrients. Increase in folate-rich foods alone may not be sufficient to bring folate levels up to the RDA; supplementation is necessary in the absence of folate-fortified cereal, especially in the periconceptional period. Iron-rich foods are effective in addressing dietary iron deficiency.

Interventions involving changes in dietary behaviour need to be based on behavioural theory.

It is important to remember that the short-term nature of existing food-support programmes may be one of the reasons for a lack of evidence in their favour.

5.8 Recommendations for research

- Studies of deficiencies in dietary intakes and nutritional deficiencies among low-income and other disadvantaged childbearing women in the UK are needed to develop aims and objectives of food-support programmes.
- There is a need to develop robust study designs such as RCTs to measure the effectiveness and cost-effectiveness of food-support programmes that are part of the entitlements of low-income childbearing women. Blinding at outcome assessment and intention-to-treat analysis need to be incorporated into the methodology.
- Studies of food-support programmes targeting very young mothers and minority ethnic groups are needed.
- There is a need to include measures of smoking and breastfeeding in all evaluations of food-support programmes.
- Any such studies will need reliable methods of assessing nutrient intakes of participants.
- There is a need to study the effect of food-support programmes on outcomes such as maternal exhaustion, perinatal depression, maternal psychological wellbeing, and the impact on long-term health and nutrition of women and their babies.
- Studies of other methods of offsetting food insecurity within poor households such as income support for food purchase will be useful.
- The characteristics of better quality programmes need to be studied to examine their impact on perinatal outcomes.
- Studies also need to investigate women's views of what would make a difference to their nutrition status during pregnancy and early motherhood; their views about food-support programmes; their food preferences; their own needs for nutrition information; and how they use supplements offered to them with regard to distribution within the household.

The successor to the Welfare Food Scheme in the UK, Healthy Start, needs to be evaluated through a well-designed prospective study. It is possible to achieve this by rolling out the programme in stages in different regions of the country, so creating an opportunity to compare the old and the new programme in a controlled trial. For effectiveness, Healthy Start should undertake to study:

- mean birth weight
- head circumference at birth
- uptake of supplements
- women's dietary intakes
- maternal weight gain
- nutrition knowledge and awareness
- uptake of nutrition education and antenatal care
- impact on nutritional intake among other family members
- women's views of the changes in programme content and delivery
- savings achieved to the household
- costs of the programme to the government.

The impact on subsequent pregnancies, breastfeeding and family nutrition need to be examined. A priori sample size calculation and appropriate analysis of the data would ensure the validity of the findings of the study. Such a study would allow for further refinement and development of the programme.

6 Summaries of effectiveness

These summaries are based on the strength of evidence generated from studies that met at least some of the quality criteria for the review.

Box 1: Evidence of effectiveness – WIC

- Prenatal WIC participation is *likely* to result in increased maternal weight gain; this effect is enhanced when participation begins earlier in pregnancy and lasts longer
- Prenatal WIC participation is *likely* to result in increased intakes of energy, protein, vitamin B6, iron, thiamin, riboflavin, vitamin C and calcium
- Prenatal WIC participation is *likely* to result in higher energy intake among heavy smokers
- Postpartum WIC participation is *likely* to result in increased haemoglobin concentration, and reduced rates of anaemia among non-lactating women, if participation is uninterrupted for 6 months
- Prenatal WIC participation is *likely* to result in increased newborn head circumference
- Prenatal WIC participation is *likely* to result in reduced rates of premature rupture of membranes
- Prenatal WIC participation is *likely* to result in more women receiving nutrition counselling sessions and more receiving more than two sessions
- Mean birth weight of babies born to smokers, particularly heavy smokers, *probably* improves as a result of prenatal WIC participation
- Higher programme quality *may* improve perinatal outcomes
- Prenatal WIC participation is *unlikely* to lower rates of low birth weight
- Prenatal WIC participation is *unlikely* to raise mean birth weight
- Prenatal WIC participation is *unlikely* to lower rates of pre-term birth or increase duration of gestation
- Prenatal WIC participation is *unlikely* to increase frequency of prenatal care
- Prenatal WIC participation *probably* does not result in increased maternal haemoglobin concentration
- Prenatal WIC participation *probably* does not have an effect on reduction in the time women work outside the home during their pregnancy
- There is insufficient evidence of effect of prenatal WIC participation on fetal survival

Box 2: Evidence of effectiveness – Stand-alone energy-protein supplements

- Stand-alone high-protein supplements are *very likely* to result in early pre-term births among women who had adequate protein intake at baseline
- Stand-alone high-protein supplements are *very likely* to result in intrauterine growth retardation among women who had adequate protein intake at baseline
- Stand-alone balanced protein-energy and high-protein supplements are *very unlikely* to result in increased mean birth weight among all study participants (smokers + non-smokers)
- Stand-alone balanced protein-energy supplement is *very likely* to result in an increase in length of gestation
- Stand-alone balanced protein-energy and high-protein supplements are *likely* to result in an increase in mean birth weight of babies born to heavy smokers
- Stand-alone high-protein supplements are *likely* to result in improvement in some infant psychological outcomes at 1 year
- Stand-alone protein-energy supplements are *unlikely* to improve somatic outcomes in infants

Box 3: Evidence of effectiveness – Nutrition education and/or counselling of pregnant women

- Nutrition education interventions aimed at improving poor diets are *likely* to improve intakes of calcium, protein, carbohydrate, vitamin C, niacin, riboflavin and thiamin but not iron or fat intake
- Nutrition education interventions aimed at improving poor diets are *likely* to reduce the proportion of women with low levels of calcium, ascorbic acid and riboflavin
- Nutrition education aimed at reducing the risk of gestational diabetes in a high-risk group is *likely* to result in improvements in folic acid intake at 6 months postpartum
- Nutrition counselling *may* have an impact on maternal weight gain
- Nutrition counselling *may* have an impact on mean birth weight
- Nutrition education targeting a high risk group is *unlikely* to reduce their risk of developing gestational diabetes, reduce their maternal energy intake during pregnancy, or reduce mean birth weight of their babies
- Nutrition counselling probably has no impact on rates of low birth weight
- Nutrition counselling probably has no impact on gestational age at birth, newborn head circumference or length at birth

Box 4: Evidence of effectiveness – Complex health and social care interventions including a nutrition component delivered prenatally in women's homes

- Complex health and social care interventions are *very likely* to reduce rates of pre-term birth among heavy smokers ($\geq$ 15 cigarettes/day)
- Complex health and social care interventions are *very likely* to reduce the number of cigarettes smoked each day
- Complex health and social care interventions are *very unlikely* to have a favourable impact on low birth weight and mean birth weight
- Complex health and social care interventions are *very unlikely* to have a favourable impact on gestational age at birth
- Complex health and social care interventions are *unlikely* to have an impact on maternal weight gain
- Complex health and social care interventions *may* have a small impact on mean birth weight of babies born to very young mothers

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(The table numbers of included studies in Appendix 3 are shown at the end of the relevant references)

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APPENDIX 1

Search strategy

MEDLINE

1. wic.ti,ab.
2. (special supplemental nutrition program for women infants and children).ti,ab.
3. (supplemental nutrition program for women infants and children).ti,ab.
4. (supplemental food program for women infants and children).ti,ab.
5. (women infants and children supplemental nutrition program).ti,ab.
6. (women infants and children supplemental food program).ti,ab.
7. (women infants and children).ti,ab.
8. (food and nutrition service).ti,ab.
9. (expanded food and nutrition education program).ti,ab.
10. efnep.ti,ab.
11. welfare food scheme.ti,ab.
12. healthy start.ti,ab.
13. sure start.ti,ab.
14. surestart.ti,ab.
15. lifeskills in food education.ti,ab.
16. nutrition education network.ti,ab.
17. nutrition integrity.ti,ab.
18. (food and money basics).ti,ab.
19. food stamp program.ti,ab.
20. community mothers programme.ti,ab.
21. protection maternelle et infantile.ti,ab.
22. protection maternelle et infantile.ot,ab.
23. healthstart.ti,ab.
24. farmers market nutrition program$.ti,ab.
25. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. (food adj2 (stamp$ or voucher$ or token$ or coupon$ or cash or bank$ or pantry or pantries)).ti,ab.
27. food scheme$.ti,ab.
28. food program$.ti,ab.
29. (food adj2 assistance).ti,ab.
30. food$ insecurity.ti,ab.
31. (food adj2 support$).ti,ab.
32. welfare food$.ti,ab.
33. community food$.ti,ab.
34. (feeding adj2 (program$ or scheme$ or project$)).ti,ab.
35. food services/
36. supermarket voucher$.ti,ab.
37. (soup kitchen$ or collective kitchen$ or community kitchen$).ti,ab.
38. ((food or diet$ or nutrition) adj2 intervention).ti,ab.
39. (26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38) and (mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum).ti,ab.
40. maternal nutrition/
41. (maternal welfare/ or maternal health services/) and (food$ or diet$ or nutrition or nutrient$).ti,ab.
42. (prenatal care/ or preconception care/) and (food$ or diet$ or nutrition or nutrient$).ti,ab.
43. ((malnourish$ or undernourish$ or undernutrition) adj2 (mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum)).ti,ab.
44. (malnutrition/ or deficiency diseases/) and (mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum).ti,ab.
45. (fruit/ or vegetables/) and (mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum).ti,ab.
46. 40 or 41 or 42 or 43 or 44 or 45
47. exp Health Education/
48. exp Health Promotion/
49. exp Health Behavior/
50. exp Health Knowledge, Attitudes, Practice/
51. exp communications media/
52. (television or video or radio or internet or book$ or booklet$ or leaflet$ or pamphlet$ or newspaper$ or magazine$).ti,ab.
53. counseling/ or (counselling or advice).ti,ab.
54. health information.ti,ab.
55. 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54
56. (mother or mothers or maternal or childbear$ or pregnant or pregnancy or breastfeed$ or breast feed$ or lactating or lactation or periconcept$ or preconcept$ or postnatal or prenatal or postpartum).ti,ab,sh.
57. (food or diet or nutrition or nutrient$).ti,ab.
58. vitamin a/ or vitamin c/ or vitamin d/ or vitamin b6/ or

dietary, iron/ or zinc/ or dietary, calcium/ or folates.ti,ab. or folic acid/ or magnesium/ or selenium/ or dietary, fats/ or dietary, proteins/ or dietary, carbohydrates/ or micronutrient$.ti,ab. or macronutrient$.ti,ab. or multivitamin$.ti,ab.
59. 55 and 56 and (57 or 58)
60. ((nutrition or food or diet$) adj educat$).ti,ab. and 56
61. 59 or 60
62. 25 or 39 or 46 or 61
63. animals/
64. human/
65. 63 not (63 and 64)
66. 62 not 65
67. exp asia/ or exp africa/ or exp south america/
68. 66 not 67
69. (comment or letter or editorial).pt.
70. 68 not 69

Interface used, database coverage, search date, numbers of records retrieved

MEDLINE
Via Ovid
Date coverage: 1966 to November week 3 2004
Search date: 13/12/04
Records retrieved: 2954

EMBASE
Via Ovid
Date coverage: 1980 to 2004 week 50
Search date: 14/12/04
Records retrieved: 3272
Records retrieved after de-duplication: 2193

CINAHL
Via Ovid
Date coverage: 1982 to December week 1 2004
Search date: 14/12/04
Records retrieved: 1093
Records retrieved after deduplication: 584

PsycINFO
Via Silverplatter
Date coverage: 1872 to 2004/12 week 1
Search date: 17/12/04
Records retrieved: 869
Records retrieved after deduplication: 711

SOCABS
Via CSA Internet Database Service
Database coverage: 1963 to current
Search dates: 21/12/04 and 22/12/04
Records retrieved: 282
Records retrieved after deduplication: 207

Science Citation Index
Via Web of Science
Database coverage: 1945 to present (20/12/04)
Search date: 23/12/04
Records retrieved: 3049
Records retrieved after deduplication: 1608

Social Science Citation Index
Via Web of Science
Database coverage: 1945 to present (20/12/04)
Search date: 23/12/04
Records retrieved: 1318
Records retrieved after deduplication: 702

The Cochrane Central Register of Controlled Trials (CENTRAL)
Wiley Interscience interface
Issue searched: 2004 issue 4
Search date: 18/1/05
Records retrieved: 316
Records retrieved after deduplication: 152

SIGLE
Via Webspirs
Database coverage: 1980 to 2004/06
Search date: 6/1/05
Records retrieved: 81
Records retrieved after deduplication: 80

DARE
Via the CRD internal/administrative version using CAIRS software
Date coverage: 1992 to 2005
Search date: 18/1/05
Records retrieved: 73
Records retrieved after deduplication: 59

Cochrane Database of Systematic Reviews
Via Wiley Science interface
Issue searched: Cochrane library 2004 issue 4
Search date: 25/1/05
Records retrieved: 61

Trip Database plus
Via www.tripdtabase.com
Search date: 18/1/05
Records retrieved: 23
Records retrieved after deduplication: 0

HealthProm*is*
Search date: 31 January 2005
Search date: 31/1/05
Records retrieved: 18, 49, 12, 22, 14, 30, 2, 57, 135, 133, 13

Food Science and Technology Abstracts
Via Dialog File 51
Database coverage: 1969-2005/Jan W5
Search date: 7/2/05
Records retrieved, stage 1: 254
Records retrieved, stage 2: 1

CAB Abstracts
Via Dialog File 50
Database coverage: 1972 to Jan 2005
Search date: 7/2/05
Records retrieved, stage 1: 2831
Records retrieved, stage 2: 5

In addition to the bibliographic databases, a number of web-based resources were also searched. These were the ReFer database, NCCHTA webpages, SIGN guidelines webpages, NICE webpages, National Guidelines Clearinghouse webpages, Clinical Evidence, and the National Research Register. Paper copies of the results for all of these resources were printed and passed to the reviewer for scanning. Details of the search dates, records retrieved and the searches used are given below.

ReFer
Via www.info.doh.gov.uk/doh/refr_web.nsf/Home?OpenForm
Search date: 19/1/05
Records retrieved: 112

NCCHTA webpages
Via www.ncchta.org
Search date: 6/1/05
Records retrieved: 9

SIGN guidelines webpages
Via www.sign.ac.uk/guidelines/index.html
Search date: 6/1/05

NICE webpages
Via www.nice.org.uk
Search date: 6/1/05
19 items identified.

National Guidelines Clearinghouse
Via www.guideline.gov
Search date: 6/1/05
Nutrition retrieved 332 guidelines
Food retrieved 424 guidelines
Diet retrieved 246 guidelines

Clinical Evidence
The paper version of Clinical Evidence issue 12 December 2004 was scanned

National Research Register
Via CD ROM version
National Research Register 2004 issue 4
Search date: 18/1/05
Total retrieved from all searches of NRR = 59+99+52=210
5 records selected for possible inclusion

APPENDIX 2

Pre-screen form

Author, year		
1st Reviewer	Decision*	Date
2nd Reviewer	Decision*	Date

Please circle your answer to a question and tick relevant boxes with ✓ or ✕

1 Is the publication concerned with childbearing women? Yes / No

2 Were these women in need of specialised dietary care (eg diabetes)? Yes / No

3 Is the publication about any of the following nutrition interventions? Yes / No

Food supplementation	Micronutrient supplementation
Milk tokens	Food stamps
Nutrition/ health education	Nutrition counselling
Training of practitioners	Practical support (shopping, cooking)
Social support including information, tangible practical support, emotional support	

4 Does the publication report an evaluation study of the above intervention? Yes / No

5 Was the study design any of the following? Yes / No

RCT	CT with concurrent controls
Before/after study (cohort or cross-sectional)	Systematic/structured review**

6 Were any of the following outcomes reported? Yes / No

Intrauterine growth retardation	Gestational age at birth
Birth weight	Pre-term birth
Perinatal mortality	Infant mortality
Change in pre-pregnancy weight	Infant weight gain
Maternal/ infant nutritional status	Micronutrient status
Cost outcomes	

7 Was the study set in one of the following countries? Yes / No

Australia	Austria	Belgium	Canada
Denmark	Finland	France	Germany
Greece	Iceland	Ireland	Italy
Japan	Luxembourg	Netherlands	New Zealand
Norway	Portugal	Spain	Sweden
Switzerland	UK	USA	

8 Is the publication available in English? Yes / No

Consider for data extraction if answers to 1, 3–7 are yes
Reject if answer to any of 1, 3–7 are no; or if answer to 2 is yes

* Code DX (consider for data extraction) or R (reject on pre-screening) or D (discuss).
** Reviews are to be retrieved and screened for primary studies – not for inclusion in their own right.

APPENDIX 3

Data extraction tables for included studies

Key to tables (some abbreviations are noted in footnotes to tables):

CT= controlled trial
RCT = randomised controlled trial
C = control
I = intervention
s/ns = significant/not significant
n = number
SD = standard deviation
SE = standard error
SEM = standard error of mean
LBW = low birth weight
MBW = mean birth weight
p = p value
g = gram
L = litre

Strength of evidence key

++ all or most of the quality criteria fulfilled
+ some of the criteria fulfilled
– few or no criteria fulfilled

Table 1: WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Bailey 1983 USA **Research aim** To compare levels of vitamin B6, iron and folacin in pregnant women participating in WIC with a matched control group **Study design** Non-randomised CT **Method of group allocation** Participants of WIC centres were allocated to the intervention group; women attending clinics in another county without WIC programme allocated to control group **Unit of allocation** Individual women **Unit of analysis** Women Newborns **Sample size calculation** Not reported **Sample size achieved** 89 [I = 43; C = 46] **Outcome measures** – Birth weight – Dietary intake of B6, iron, folacin, energy, protein – Serum iron – Serum folacin – Red blood cell folacin – Plasma plasma pyridoxil phosphate (PLP) – Haematocrit **Method of dietary assessment** 24 hour recall	**Selection** – Experimental group recruited from Maternity and Infant Care project in Alachua county, Florida – Control group from Putnam county health department **Inclusion criteria** – 30 weeks gestation – High nutritional risk (anaemia, obesity, short inter-pregnancy intervals, abnormal pregnant weight gain, age, and inadequate nutritional pattern). Not clear if some or all these criteria were met **Exclusion criteria** Not stated	n I = 43 C = 46 **Ethnicity black** n % I: 27 62 C: 27 59 **Ethnicity white** n % I: 16 37 C: 19 41 **Primigravida** n % I: 27 62 C: 27 59 **Age in years** mean [SD] I: 21 [4] C: 22 [6] **Age < 18 years** n % I: 11 25 C: 13 28 **Gestation at enrolment** = 30 weeks for both groups Medical care identical for both groups **Group comparability at baseline** Control and Experimental groups were similar in economic and nutritional risk	**Intervention** WIC components of early 1980s included fortified breakfast cereal, fortified with iron but not with folacin – Dietary counselling at ≥ 1 clinic visit before study – Daily vitamin supplements of 250mg ferrous sulphate + 800mcg folacin – Routine medical care **What controls got** – Dietary counselling at ≥ 1 clinic visit before study – Iron 250mg ferrous sulphate and 800mcg folacin supplements – Routine medical care	**Statistical techniques** – Analysis of variance used for effect of age, ethnicity and WIC participation on nutrient intake, biochemical measures and pregnancy outcomes – Multiple linear regression analysis used to determine effects of maternal variables on birth weight and Apgar scores – 2-tailed t-tests were used to evaluate differences between WIC and control populations for all parameters – Significance was taken as $p < 0.05$ **Data collection methods** – At interview a 24 hour dietary recall (Frank et al. 1977)* conducted by a nutritionist using food models and measuring devices – Nutrient Dietary Data Analysis System used for computation of nutrient intakes (Endres and Sawicki 1979)** – Blood samples collected for biochemical analyses **RESULTS** I / C / p **LBW (> 2500g) %** 5 / 10 / ns **MBW (n) mean, g [SD]** (37) 3229 [546] / (42) 3276 [563] / ns **MBW babies born to smokers (n) mean, g [SD]** (10) 3286 [515] / (14) 2976 [596] **MBW babies born to non-smokers (n) mean, g [SD]** (25) 3218 [538] / (22) 3461 [520] NOTE: Birth weights of babies born to smokers were lower than birth weights of babies born to non-smokers in control group ($p < 0.05$); differences in birth weights of babies born to smokers and non-smokers in WIC group not significant **Haematocrit (n) mean, % [SD]** (42) 35 [3] / (48) 35 [5] / ns **Low haematocrit (< 32%), %** 17% / 29% **Serum iron (n) mean [SD], mcg/dL** (31) 106 [44] / (57) 99 [42] / ns **Transferrin saturation (n) mean, % [SD]** (28) 37 [23] / (54) 23 [10] / < 0.05 **Low transferrin saturation (< 15%), %** 8% / 15% **Plasma pyridoxil phosphate (n) mean, mg/mL, [SD]** (40) 4.6 [6.8] / (35) 3.3 [1.8] / ns **Serum folacin (n) mean, ng/mL [SD]** (42) 14 [11] / (57) 26 [26] / < 0.05 **RBC folacin (n) mean, ng/mL [SD]** (42) 353 [278] / (57) 602 [321] / ns Dietary intakes of iron and vitamin B6 were significantly higher in the intervention (WIC) group. Folate intakes were < 35% RDA in both groups. Energy and protein intakes were higher than RDA in both groups **Costs:** Not reported **Views:** Not reported * Frank AC, Berenson AS, Scilling PE et al. (1977) Adapting the 24-hour recall for epidemiological studies of school children. *Journal of the American Dietetic Association* 71:26–31. ** Endres J, Sawicki M (1979) *Nutrient Dietary Data Analysis Guide*. Carbondale, IL: Southern Illinois University.	Losses and drop-outs are not reported in the paper. There are mis-matches in reported numbers – baseline characteristics (I 43; C 46), dietary intakes (I 41; C 37), biochemical values (I 8–42; C 35–57); and birth weight (I 37; C 42). It is probable that data for all were not available, but this does not account for excess numbers for biochemical values, up to 57	No information on length of participation in WIC; or trimester of entry to WIC. No information regarding participation in smoking cessation programmes, and if any, was there a difference in participation between intervention and control groups. Further, significance tests were not conducted for differences among smokers in both groups, and non-smokers in both groups **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 2: WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant* selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Collins et al. 1985 USA **Research aim** To test the hypotheses: – If the WIC supplemental food programme is effective, the participants who are by definition at nutritional risk will attain the same pregnancy outcomes as the non-participating controls – If educational component of the WIC programme is effective then participants should attain a higher level of use, practice and knowledge than control subjects **Study design** Controlled trial **Method of group allocation** Not clear **Unit of allocation** Individual woman **Unit of analysis** Woman Newborns **Sample size calculation** Not reported **Sample size achieved** 519 [I = 341; C = 178] **Outcome measures** – Birth weight – Maternal weight gain – Pregnancy-related knowledge; health-related knowledge; health-related practices **Method of dietary assessment** Not reported	**Selection** From public health department clinics including prenatal, WIC, wellbaby, maternal and child health clinics in six Appalachian Regional Commission counties in Alabama, 1980–1981 **Inclusion criteria** Women attending public health clinics **Exclusion criteria** Women at high risk of obstetric complications * Sample size, participant selection and characteristics reported in this table are with reference to women participants only (not infants and children)	I / C / s/ns n 341 / 178 **Mean age in years** 22.5 / 22.2 / ns **Education (mean grade completed)** 10.9 / 11.0 / ns **Married** 42.1% / 51.1% / s **Medicaid cover** 40.9% / 18.5% / p < 0.01 **Annual income < $8000** 89.7% / 82.2% / p < 0.03 **No children at time of interview** 45.1% / 48% / ns **Ethnicity: white** 37.8% / 38.2% / ns **Ethnicity: black** 62.2% / 61.8% / ns **Smoker** 32.6% / 33.3% / ns **Group comparability at baseline** The groups were not comparable for socio-economic status and Medicaid cover – they were more affluent women who were comparable for age, ethnicity and smoking status at the time of the interview	**Intervention** WIC provision in early 1980s – food supplements plus nutrition education **What controls got** Not clear	**Statistical techniques** – Statistical significance determined by means of chi-square tests and two independent sample t-tests – Yates corrected chi-square test used if variable had two categories – Significance was taken as $p \leq 0.05$ **Data collection methods** – Dietary intake assessment not reported – Structured interview collecting data on healthcare use, health-practices, health knowledge and pregnancy outcomes – Data extracted from birth certificates, medical records and WIC records after delivery **RESULTS** I (n = 341) / C (n = 178) / p These figures are the numbers of women recruited to each group; it is assumed that percentages reported in the paper were based on numbers recruited **Low birth weight (< 2.5kg), %** 6.4 / 3.8 / ns **Birth weight mean, kg** 3.2 / 3.2 / ns **Preterm birth, %** 5.4 / 4.9 / ns **Mean maternal weight gain, kg** 11.7 / 11.3 / ns Approximately 20% I group women and 15% C group women gained more than 16kg during the pregnancy **Taking iron supplements, %** 88.3 / 72.3 / < 0.01 **Discussed infant feeding with practitioner, %** 68.8 / 50.3 / < 0.01 **Women planning to breastfeed, %** 18.5 / 16.4 / ns Among women planning to breastfeed, more WIC participants gave the reason that nursing is more convenient; and more responded that breast milk is better **Smoking in pregnancy, %** 32.6 / 33.3 / ns **Drinking alcohol during pregnancy, %** 22.6 / 27 / ns Differences in pregnancy complications between the groups not significant except for albumin in urine p = 0.02 No differences in percentage of control and WIC women receiving prenatal care and timing of the first prenatal visit **Costs:** Not reported **Views:** Not reported	Not reported	– Control women were not at nutritional risk – Sensitivity of nutritional risk assessment not assessed **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 3: WIC before-after study (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Edozien et al. 1979 USA **Research aim** To determine if there was 'sufficient' malnutrition among the target population to justify a remedial programme and, if so, to determine if the WIC programme produced a measurable improvement in the nutritional status of the participants **Study design** Before-after (paper reports 'data for intervention group after they had received food supplements (was) compared with data from control group taken in the time period before the intervention started') **Method of sample selection** Not clear Women in or out of the WIC programme were studied **Unit of allocation** Individual women **Unit of analysis** Women Newborns **Sample size calculation** Not reported **Sample size achieved (women only)** 9867 (5742 pregnant; 4125 postnatal)	**Selection** 18 projects in 14 states between November 1973 and June 1976 **Inclusion criteria** Not reported **Exclusion criteria** Not reported * Sample size, participant selection and characteristics reported in this table are with reference to women participants only (not infants and children)	All national evaluation study participants – households falling below the Office of Economic Opportunity (US government) poverty line n = 9867 women (5742 pregnant; 4125 postnatal) The following details relate to all study participants – women, infants and children **Urban residents** 91.6% **Rural farm residents** 2.6% **Rural non-farm residents** 6.0% **Average annual after tax income** $3757 **Eligible for food stamps** 84.2% **Ethnicity** white 21% black 34% Spanish-America 42% Native American 3%	**Intervention** Food supplement provided each month for pregnant and lactating women: 29.33L milk; cheese as milk substitute (0.453kg = 2.83L milk); 2.5 dozen eggs, 4 x 0.226kg packages of iron fortified cereal; 6 x 1.36L cans of fruit juice **Eligibility for WIC enrolment** – Pregnancy – Postpartum to 6 weeks if not breastfeeding – If breastfeeding then up to 1 year postpartum – Certified for having: inadequate nutritional patterns, nutritional anaemia, inadequate/ deficient patterns of growth, history of prematurity or miscarriage – Residing in a project area – Eligibility for free or reduced cost medical treatment **What controls got** Not clear	**Statistical techniques** – Multiple regression analysis – Statistical significance of differences between groups was indicated by a p value (considered significant if p value was < 0.05) **Data collection methods** – 24 hour dietary recall from half the women at enrollment – Women examined every 3 months until delivery and at 4 and 8 weeks postpartum – Vital statistics from medical and birth records – Blood samples RESULTS **Birth weight adjusted for gestational age by number of months participation in WIC, (n), mean, g** Participation (n) mean, g 0 months (41) 3057 < 3 months (421) 3052 3–6 months (412) 3125 > 6 months (139) 3193 **Duration of gestation by months of participation in WIC, (n) mean number of weeks** Participation (n) mean, weeks < 3 months (390) 38.2 3–6 months (399) 38.50 > 6 months (131) 39.07 The difference in gestational duration between < 3 months and > 6 months participation was statistically significant at 0.05 I C p **Maternal weight gain for all pregnant women (n) mean, kg** (772) 8.1 (2889) 6.8 < 0.01 **Maternal weight gain by length of gestation (n) mean, kg** 28–31 weeks gestation (130) 10 (389) 7.8 < 0.05 36–39 weeks gestation (256) 11.1 (209) 10.5 < 0.4	Unclear (paper reports 'the women returned for 5417 visits')	A large number of unaccounted for losses; notable variation in the numbers in each box – and no explanation for this in the write-up. 26% of women were > 20% overweight **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 3 (cont.) WIC before-after study (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Outcome measures – Birth weight – Rate of low birth weight – Rate of miscarriage – Still birth rate – Prematurity rate – Infant mortality rate – Medical complications of pregnancy – Maternal weight gain during pregnancy – Dietary intakes – Biochemical indices **Dietary assessment** 24 hour dietary recall		**Average household size (number of persons)** 4.6 **Mean age at enrolment [SD]** 23 [5.7] **Overweight by 10–20%** 15% **Overweight by > 20%** 26% **Group comparability at baseline** Not clear		See results below		

Increases in daily nutrient intake between initial and follow-up visits

	Women > 3 months pregnant (n = 299)	Postpartum women (n = 421)
Protein, g	+4.6	
Calcium, mg	+123.0	
Phosphorous, mg	+107.0	
Iron, mg	+1.0	
Thiamin, mg	+0.10	+0.15
Riboflavin, mg	+0.22	
Ascorbic acid, mg	+17.0	+26.0

(Based on dietary assessment of half the sample)

Percentage of women with anaemia* by duration of gestation and participation in WIC (n) %

	Initial visit	< 3 months in WIC	> 3 months in WIC	p
< 17 weeks	(1984) 13	–	–	–
17–28 weeks	(2750) 29	(324) 23	(229) 28	ns
> 28 weeks	(1379) 27	(346) 15	(646) 18	< 0.05
Postpartum	(462) 24	(441) 16	(1191) 12	< 0.05

No significant changes in percentage of pregnant women with < 15% transferrin saturation

Plasma cholesterol reduced by 9mg/100mL between initial and follow-up visit of postpartum women who had participated in WIC for > 3 months; differences observed for pregnant women at initial and follow-up visit were not significant

Costs: Not reported

Views: Not reported

* Hb ≤ 11g/100mL during pregnancy and 12g/100mL postnatally are considered as anaemia; haemoglobin levels reported in this set are approximate

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 4: WIC RCT (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Metcoff et al. 1985 USA **Research aim** To test the hypothesis: 'If WIC supplementation improved birth weight, it should have a positive effect on maternal nutriture, including plasma nutrient levels and leukocyte protein syntheses' **Study design** RCT **Method of randomisation** Computerised random numbering **Unit of allocation** Individual women **Unit of analysis** Woman Newborn **Sample size calculation** Not clear. 'A pre-tested equation based on an earlier study* was used to estimate the number of women predicted to deliver either low, average-weight or large babies' * Metcoff J, Costiloe P, Crosby W et al. (1981) Maternal nutrition and fetal outcome. *American Journal of Clinical Nutrition* 34:708–21.	**Selection** Women attending prenatal clinics at Oklahoma Memorial Hospital **Inclusion criteria** Eligibility for WIC (household incomes up to185% poverty level) **Exclusion criteria** Not stated	Ethnicity white 74% Ethnicity black 21% Native Americans 1% Orientals and Mexicans 4% History of delivering baby < 2500g (unadjusted for gestational age) 9% Married 57% Primipara 32.3% > 4 pregnancies 16.6% < 10 months since last pregnancy 60% > 20 months since last delivery 30% Non-smoking mothers 54% Did not drink coffee 74% Regularly used birth control pills in the 6 months before current pregnancy 14% Mean age in years 21.9 ± 4.4 Mean years in education11.3 ± 1.7 **Comparability of groups at baseline** Yes, except intervention group women weighed more at entry to study than control group (p < 0.007) I: 69.4kg ± 15.8kg C: 65.6kg ± 14.7kg No statistically significant differences in key characteristics between drop-outs and those who remained in the study	**Intervention** Vouchers exchangeable for milk, eggs and cheese (= 40–50g protein + 900–1000kcal daily) **What controls got** Regular diet containing 1.1g protein + 28kcal energy per kg/day (no supplements)	**Statistical techniques** – SAS package used for all analyses – t-tests for difference between means – Multiple regression analysis – Analysis of covariance used to adjust for groups' mean differences in confounding variables to reduce unexplained variance **Data collection** – 24 hour dietary recall – Maternal anthropometric measurements including height, weight, MUAC, skin fold thickness – Ultrasound for fetal biparietal diameter, fetal humerus and femur lengths – Nutrition related measures at 19 ± 2 weeks and 35 ± 2 weeks – plasma nutrients, plasma amino acids, leucocytes – Birth weight on scalectronix balance for newborns – Birth length, skin fold thickness, head circumference – Gestation age assessed according to Dubowitz scores RESULTS Results are presented for 410 mother-baby pairs for whom complete data were available I / C / p **Low birth weight all participants (unadjusted) (n) %** (238) 8.68 / (172) 6.9 / ns **Birth weight (unadjusted for maternal weight at entry) (n) mean, g** (238) 3254 / (172) 3163 / 0.039 NOTE: After adjusting for maternal weight at entry to study the effect of WIC on birth weights of all participants was not statistically significant **Birth weight (adjusted) of babies born to heavy smokers (> 10 cigarettes/day) (n) mean, g** (68) 3235 / (53) 3059 / < 0.017 **Gestational age of newborn (n) mean, weeks** (68) 39.5 / (53) 39.8 **Heavy smokers (> 10 cigarettes/day) maternal weight at entry (n) mean, kg** (68) 67.1 / (53) 67.5	Of the 824 eligible women in the sample, 683 were eligible for further selection; 133 dropped out of the study (ie moved from the area), seven were excluded as they had multiple births and there were 15 abortions or stillbirths	Of the 824 eligible women in the sample, 471/683 women were enrolled at mid-pregnancy based on a prediction of birth weight; 126 pregnant women were considered at high risk and 293 women were also selected to have babies in the middle and upper tertiles of birth weight. A third of the selected sample of 471 women were assigned to the unsupplemented control group; 353 women predicted to deliver average-sized babies were not included in the study Results are presented for 410 women who completed the study, 226 were predicted to have small or large babies and 184 to have average-size babies. This presents some difficulties with interpretation. Furthermore, the results of birth weight are clinically unimportant – there are no actual numbers except for the sub-sample of mothers who smoked **Strength of evidence** +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight; MUAC = mid-upper-arm circumference
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 4 (cont.): WIC RCT (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Sample size achieved 676 recruited 471 randomised Outcome measures – Birth weight – Dubowitz score – Anthropometric measurements of baby and mother – Plasma iron – Total iron binding capacity – Folic acid – Maternal granulocyte protein synthesis Dietary assessment 24 hour recall		Average household size (number of persons) 4.6 Mean age at enrolment [SD] 23 [5.7] Overweight by 10–20% 15% Overweight by > 20% 26% Group comparability at baseline Not clear		Mean difference in maternal weight at study entry (19 weeks) between I and C group + 3.8kg favouring control group I / C / p Maternal weight at 36 weeks (n) mean [SE], kg (208) 79.3 [0.3] / (145) 76.8 [0.3] / 0.057 Biceps skin fold thickness (n) mean [SE], mm (199) 16.2 [0.5] / (142) 14.7 [0.6] / 0.059 Leucocyte protein synthesis (n) p moles 3 H-leucine/h (163) 126.6 [2.6] / (96) 115.2 [3.5] / 0.009		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; SE = standard error; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 5: WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Pehrsson et al. 2001 USA **Research aim** To measure the impact of WIC participation on biochemical postpartum iron status of non-lactating women over 6 months after delivery **Study design** Controlled trial **Method of group allocation** Intervention group from select WIC sites; controls selected from adjoining counties **Unit of allocation** Individual woman **Unit of analysis** Woman Newborn **Sample size calculation** Not reported **Outcome measures** – Dietary intake – Haemoglobin – Plasma transferrin receptor – Plasma ferritin **Dietary assessment** Food frequency quest	**Selection** From Maryland WIC agencies – Study group from Baltimore city sites – Control group from Prince Georges and Montgomery Counties **Inclusion criteria** – Delivery of full term infant in previous month – No breastfeeding – No major medical problems – Certification as 'low-risk' applicant – English-speaking **Exclusion criteria** age <19 years	I C n 57 53 **Age – mean in years [mean ± SE]** 24.9 [0.6] 25.4 [0.6] **Ethnicity, n (%)** White 7 (13) 12 (21) African-American 46 (87) 45 (79) **≤ 2 years between two most recent pregnancies, n (%)** 21 (39.6) 23 (40.3]) **Smoking n (%)** 0 43 (75) 46 (87) < 10/day 10 (18) 3 (6) ≥ 10/day 4 (7) 4 (7) **Participation in food stamp programme, n (%)** 28 (49) 24 (45) **Use of prenatal supplements, n (%)** 30 (53) 26 (49) **Received WIC vouchers during ≥ last trimester of pregnancy, n (%)** 48 (84) 52 (98) **Prenatal nutrition education, % p** 84 96 < 0.05 **Group comparability at baseline** No significant differences in demographic, health and reproductive characteristics were noted between non-lactating postpartum WIC participants and control group. More women in the control group received WIC vouchers in the last trimester of pregnancy. Prenatal nutrition education was significantly more in the control	**Intervention** WIC food support and nutrition education during the postpartum period **What controls got** Not clear; they were not certified with WIC during the postpartum period	**Statistical techniques** – SAS software used – Student's t-tests used for differences between participants and non-participants in time intervals between delivery and visits – Student's t-tests and chi-square tests for differences at baseline and at each visit between the two groups – Partial correlation coefficients were determined between Hb, TfR and ferritin collected at 30 days and at 2, 4, 6 months postpartum **Data collection** – Low literacy food frequency questionnaire to assess consumption of foods affecting iron status (did not measure actual intake, only ranks intakes relative to other participants intake) – Demographic data from WIC records – Height, weight and blood samples for Hb, TfR and ferritin collected at 30 days, 2, 4 and 6 months RESULTS I C p **Haemoglobin (n) mean, mmol/L [SE]** At 0.5 months postpartum (57) 7.88 [0.12] (52) 7.88 [0.12] ns at 2 months postpartum (48) 7.82 [0.12] (46) 7.63 [0.06] ns at 4 months postpartum, mmol/L (46) 7.88 [0.12] (44) 7.7 [0.12] ns at 6 months postpartum, mmol/L (47) 8.01 [0.12] (47) 7.63 [0.12] < 0.05 Haemoglobin levels increased over time reaching statistical significance p < 0.05 at 6 months between intervention and control groups **Women with haemoglobin concentrations < 12g/dL at 6 months postpartum, n (%)** 47 (17) (47) [51] <0.05 **Ferritin (n) mean, mcg/L [SE]** at 0.5 months (57) 56 [5] (53) 59 [7] ns at 2 months (48) 47 [6] (46) 45 [4] ns at 4 months (43) 37 [4] (45) 33 [3] ns at 6 months (45) 36 [3] (46) 35 [3] ns **Dietary intake** Mean dietary iron intake was < 75% of the RDA in both groups. No significant differences in self-reported intakes of iron or vitamin C between groups **Costs:** Introduction states that about $44 million was spent on 89,673 clients in WIC in 1995; cut-backs in the outlay resulted in only high-risk women being certified in the postpartum period **Views:** Not reported	Not clear	– Non-lactating women's recommended daily allowances were considered the same as non-pregnant women – Concurrent participation in food stamp programme, although not significant between participating and non-participating women, may have had a cumulative effect on nutrition in participating women – Nutrition education with supplement may be more effective than without supplement **Strength of evidence** +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; SE = standard error; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 6: WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Rush et al. 1988 USA **Research aim** To assess the impact of the WIC programme on mothers and their babies **Study design** Longitudinal study with controls using a three-stage sampling design **Method of group allocation** – 1st stage – primary sampling units (PSUs) selected through probability sampling of heavily populated urban areas – 2nd stage – clinics within PSUs ordered by estimates of newly registered pregnant women in each PSU – 3rd stage – all women meeting eligibility criteria in WIC clinics agreeing to participate were allocated to intervention group; all women in non-WIC clinics allocated to control group **Unit of allocation** Individual women **Unit of analysis** Woman Newborn **Sample size calculation** Probability sampling design in three stages: – 1st stage – Primary sampling units (PSUs) – 2nd stage – WIC and control clinics – 3rd stage – women registering at clinics Design intended to yield approximately 6000 women	**Selection** From WIC centres and prenatal clinics in 48 states and District of Columbia over a 4 month period in 1983 I group – before the end of the 2nd trimester C group – before the end of the 2nd trimester at onset of prenatal care from hospitals and public health clinics (in same counties as WIC but not registered) **Inclusion criteria** In 1st or 2nd trimester of pregnancy I = eligibility and acceptance for WIC C = low-income, eligible for WIC, not accepted for WIC **Exclusion criteria** – Diabetic women – Native-American tribes – more than 6 months pregnant at recruitment	Subject characteristics (all subjects) I / C **Family income, % *** < $3000 16.3 10.8 $3000-6999 31.8 26 $7000-12,999 25.6 34.3 > $13,000 9.9 12.6 **Education, % *** < 12 years 55 48 12 years 34.1 38.4 > 12 years 10.9 13.6 **Ethnicity, % *** Black 33.3 21.6 Hispanic 15.9 23.9 White non-Hispanic 48.2 50.4 Other 2.7 4.1 **Employment, % *** Mother employed 14.5 20.8 Mother unemployed 28.1 21.4 Mother housewife/student/disabled 57.4 57.9 Father living in household employed 53.0 64.6 Father living in household unemployed 42.1 30.9 Father retired, in jail, disabled 4.9 4.5 **Receipt of other benefits, % *** AFDC only 3.4 2.1 Food stamps only 28.3 21.3 AFDC and food stamps together 15.8 6.4 AFDC = Aid to families with dependent children * All distributions (by chi-square tests) were p < 0.001	**Intervention** – Food or vouchers equivalent to cereals containing ≥ 45% RDA for iron and ≤ 6g sucrose or other sugar per 28g dry weight of cereal; dried beans/peas; peanut butter; milk; cheese; juices containing ≥ 300mg/L vitamin C; eggs – Nutrition counselling/ education – Referral to other services – Individual care plans **What controls got** Control prenatal clinics offered women nutrition education/ counselling, food stamps/AFDC, Medicaid, vitamin-mineral supplements; 75% of the control clinics employed staff who spoke Spanish (33% at WIC sites)	**Statistical techniques** – All outcomes inspected before and after adjustment by simultaneous linear multiple regression analysis for potentially confounding covariates – Chi square tests – Variance ratios for each nutrient calculated from correlation coefficients between initial and follow-up intakes **Data collection** – 24 hour dietary recall at study entry and at 36 weeks for 75% participants using USDA nutrient database and information from manufacturers and other nutrient databases – Interviews for socio-demographic information, households information, medical and behavioural information of participants and fathers, prenatal care, receipt of WIC services – Anthropometric measurements – Haemoglobin concentration – Hospital delivery records for pregnancy/ birth outcomes – 1 week food expenditure diaries for a sub-sample of women – WIC voucher assistance – Clinic administration questionnaires and nutrition education programme questionnaires for WIC directors RESULTS By the time of late pregnancy follow-up, 1/4 of the control group women had enrolled in WIC – these are reported as the WIC-Control group; they were less privileged than the remaining Control group WIC / WIC-C / Control / p **Low birth weight <2501 g for groups at follow-up, adjusted, n (%)** 2708 (5.7) / 175 (4.2) / 497 (6.8) / ns **Birth weight for groups at follow-up, adjusted (n) mean, g** (2708) 3292 / (175) 3303 / (497) 3285 / ns **Duration of gestation for groups at follow-up, adjusted (n) mean, days** (2708) 279 / (175) 279.8 / (497) 279.3 / ns **Pre-term births < 33 weeks gestation for groups at follow-up, %** 0.3 / / 0.9 / <0.05 / 0.11 / 0.9 / ns **Pre-term births < 37 weeks gestation for groups at follow-up %** 9.4 / / 12.7 / ns / 8.6 / 12.7 / ns	**Losses at late pregnancy follow-up interview** WIC participants 1112 (21%) Control group 1043 (77%) **Losses for birth outcomes** WIC group 1342 (26%) Control group 300 (22%)	Control group was more affluent than the initial WIC group Programme quality was assessed by WIC programme directors – this may have implications for the association between higher programme quality and better perinatal outcomes **Strength of evidence** +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 6 (cont.): WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Sample size achieved 6563 [I:5205; C:1358] Dietary assessment 24 hour recall Outcome measures – Maternal weight gain – Duration of gestation – Birth weight – Infant growth – Choice of infant feeding method – Other outcomes (complications of pregnancy, dietary intake, fetal survival, food expenditures)		Subject characteristics of women only Mean age in years 22.23 22.60 < 0.05 Primiparas, % 44.9 46.9 ns Previous history of LBW, % 21.6 18.8 < 0.05 Group comparability at baseline Controls were more affluent and socially privileged on almost all indicators		WIC WIC-C Control p Head circumference for groups at follow-up, adjusted (n) mean, cm 34.1 33.9 < 0.05 33.9 33.9 ns Maternal weight at study entry adjusted for weight at conception (n) mean, kg (35769) 65.17 (601) 65.89 < 0.01 (216) 65.19 (601) 65.89 ns Maternal weight at follow-up, adjusted (n) mean, kg (3576) 72.17 (214) 71.86 (598) 72.17 ns Women in WIC group, lighter at entry, caught up with women in Control group by end of pregnancy. Haemoglobin concentration in late pregnancy was higher for WIC women (ns) No differences in nutrient intakes between groups at initial interview; energy intake in Control group but not in WIC group decreased by 100kcal/day by end of pregnancy WIC WIC-C Control p Energy intake at follow-up (n) mean, kcal/day (2762) 2016.1 (530) 1905.3 < 0.01 (181) 2047.4 (530) 1905.3 < 0.05 Energy intake at follow-up as % of RDA (n) [% of RDA] (2762) [84] (181) [85] (530) [79] Protein intake at follow-up (n) mean, g/day (2762) 80.76 (530) 75.54 < 0.01 (181) 81.82 (530) 75.54 ns Significant differences in favour of WIC group at follow-up for intakes of calcium, iron, magnesium, vitamins B1, B2, B3, B6, B12, and C No nutrition counselling sessions = 0 (n) % (3774)13 (743) 41.9 < 0.001 (234)17.5 (743) 41.9 ns Nutrition counselling sessions ≥ 3 (n) % (3774) 30.4 (743) 17.8 < 0.001 (234) 28.2 (743) 17.8 ns		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 6 (cont.): WIC controlled trial (Section 4.1: WIC evaluation studies)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
				WIC / WIC-C / Control / p No. of prenatal visits (n) mean no. of visits (3725) 6.97 / (230) 6.89 / (729) 7.03 / ns Breastfeeding at hospital discharge, adjusted (n), % WIC / Control at the time of study entry (1784) 59.1 / (466) 59.4 / ns Cigarette smoking No impact of WIC participation Difference in fetal deaths adjusted (n), rate + 5.9 per 1000 births Premature rupture of membranes Lower in WIC participants than initial Control group ($p < 0.001$) Programme quality (as estimated by programme managers) Strongly related to accelerated fetal growth ($p < 0.01$), rates of LBW ($p <0.01$); head circumference ($p < 0.05$) Costs: Household food expenditures were reported separately Views: > 60% in all three groups who received nutrition counselling said that the counselling had affected their eating during pregnancy		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 7: Nutritional supplements RCT (Section 4.2: Nutrition supplement interventions)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Details of intervention	Results	Losses	Additional comments, strength of evidence
Rush et al. 1980 USA **Research aim** To assess the impact of nutritional supplementation during pregnancy on fetal growth, birth weight and development of the offspring **Study design** RCT **Method of randomisation** Not stated **Unit of allocation** Mother **Unit of analysis** Infant Mother **Sample size calculation** 250 women in each of three groups needed for a mean difference of 125g in birth weight between experimental and control groups to occur by chance no more than 5% of the time by two-tailed test (a = 0.05); difference to be detected 80% of the time (b = 0.02); and allowing for 25% loss from recruitment to follow-up **Sample size achieved** 814 [I1 = 263; I2 = 272; C=279] **Outcome measures** – Birth weight – Infant weight (6 weeks) – Infant length – Head circumference – Skinfold thickness – Neonatal health parameters (temperature, heart rate, respiration, colour etc)	**Selection** From clinic of a municipal hospital in New York City serving the indigent black community between mid-December 1970 to early September 1973 **Inclusion criteria** – Ethnicity: black – English-speaking – < 30 weeks gestation at interview – < 63kg at conception – Plus at least one of the following criteria: low pre-pregnancy weight (< 149.9kg at conception, low weight gain up to the time of recruitment, at least one previous low birth weight delivery, history of protein intake < 50g in the 24 hours preceding registration **Exclusion criteria** – Request for abortion – Specific chronic health disorders – Reported recent heavy use of narcotics or heavy use of alcohol	**Subject characteristics (mothers)** I1 / I2 / C **Mean age in years [SD]** 21.5 [4.7] / 21.9 [4.8] / 21.8 [4.7] **Mean education in years [SD]** 10.9 [1.6] / 11 [1.7] / 10.8 [1.7] **Welfare participant %** 26.5 / 24.6 / 24.6 **Low protein intake %** 47.4 / 45.3 / 50.4 **Group comparability at baseline** No significant differences were noted between groups	**I1 (supplement group)** got 2 x 8oz cans/day of high protein beverage containing 40g animal protein + 470 calories + vitamins + minerals **I-2 (complement group)** got 2 x 8oz cans/day of beverage balanced energy-protein supplement containing 6g animal protein and 322 calories + vitamins + minerals Both supplements and complements were to be taken daily from ≥ 30 weeks gestation until the time of delivery Intervention was delivered at home and at clinic by a specially trained health aide **What controls got** No food supplement, only vitamin + mineral	**Statistical techniques** – Life table analysis for assessing variation among groups in length of gestation – Life tables tested by Mantel and Haenzel test – Chi-square tests (p value set at 0.05) **Data collection methods for diet** – 24 hour quantitative dietary recall at recruitment, after 2 weeks, after 6 weeks and at approximately 32 weeks gestation – Self-report of supplement use – Inventory of used cans of supplement – Urinary riboflavin levels **Other data collection** – Birth weight from hospital records – Infant anthropometric measurements, assessment of newborn maturity and systematic psychological observations by project nurse – Capillary blood for immunoglobulin levels – Placenta evaluated for gross and microscopic abnormalities – Somatic and psychological measurements including Bayley mental, Bayley motor and Object-performance tests, free play and visual habituation of infants at 1 year of age RESULTS **Low birth weight** I1 / I2 / C / p – / 11.7% / 16.3% / ns **Mean birth weight ≥ 37 weeks gestation (n) g** (193) 3112 / (209) 3103 / (197) 3088 / ns A statistically significant favourable effect of supplement and complement on birth weight was noted among women who smoked heavily (≥ 15 cigarettes/day) **Mean birth weight < 37 weeks gestation (n) g** (51) 2254 / / (64) 2587 / < 0.01 (51) 2254 / (46) 2577 / / < 0.02 **Neonatal mortality** Rates of neonatal deaths higher in I1 group between 25 and 29 weeks, but did not reach statistical significance	**Total losses** 281 **Found ineligible after recruitment** 44 **Belated refusals** 77 **Moved out of New York city** 43 **Medical reasons** 14 **Women chose to stop taking supplements** 59 **Twins** 9 **Fetal deaths** 36	Appears that statistics used have not all been described in the paper **Strength of evidence** ++

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 7 (cont.): Nutritional supplements RCT (Section 4.2: Nutrition supplement interventions)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Details of intervention	Results	Losses	Additional comments, strength of evidence
Dietary assessment 24 hour recall				Maternal weight gain Total, average and early weight gain were significantly related to indices of dietary intake for those who entered the programme < 15 weeks; women who entered > 15 weeks did not show significant total or average weight gain I1 I2 C p Maternal weight gain total, kg 10.57 10.61 9.81 ns Average maternal weight gain/week, kg 0.44 0.43 0.41 ns Early maternal weight gain, kg/week 0.45 0.39 < 0.05 0.40 0.39 ns There was an increment in maternal weight gain among women getting the high protein supplement (I1) and enrolling early, but this did not translate into increase in birth weight Caloric intake from supplement In the I1 group an estimated 326 calories were taken daily from the beverage, 20% of which substituted regular diet; corresponding figures for I2 group were 233 calories and 11% Mean protein intake from supplement, g/ay I1 I2 C 1974 RDA 102 83 79.3 76 Infant outcomes Mean head circumference (n) cm at 1 year of age (204) 46.03 (208) 45.97 (219) 46.03 ns – No significant effect of supplement was found in somatic measurements of infants < 1 year – Significant differences observed for three psychological measures, habituation, dishabituation and length of play episodes, in favour of I1 group **Costs:** Not reported **Views:** Not reported		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 8: Nutritional supplements controlled trial (Section 4.2: Nutrition supplement interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Details of intervention	Results	Losses	Additional comments, strength of evidence
Viegas et al. 1982a UK **Research aim** To test the effectiveness of unselective dietary protein energy supplementation on fetal growth and maternal nutritional state of Asian mothers **Study design** Controlled trial **Method of group allocation** Designed to give the same distribution as parity, abnormal past obstetric history and history of early bleeding in current pregnancy – further detail not provided **Unit of allocation** Individual women **Unit of analysis** Women, newborns **Sample size calculation** Not a priori calculation. (The sample size achieved of PEV and V groups would have allowed a difference of 150g to be significant at the 5% level) **Sample size achieved** 153 (47, 50 and 45 in each of three groups) **Outcome measures** – Maternal weight gain – Maternal triceps, biceps, subscapular skinfold thickness – Maternal MUAC – Maternal plasma albumin, plasma ribonuclease activity – Birth weight – Newborn triceps skinfold thickness – Newborn MUAC – Mean placental weight **Dietary assessment** – 24 hour recall – Weighed diet periods (3–7 days)	**Recruitment** Asian mothers booking for antenatal care at Sorrento Maternity Hospital, Birmingham, UK between 25 April and 29 October 1979 **Inclusion criteria** – Booking before 20 weeks pregnancy – Living within domiciliary midwives' areas 9 and 10 in the Birmingham Area Health Authority **Exclusion criteria** Not clear	PEV / EV / V **Age in years, mean [± SD]** 25.3(5.9) / 24.7(5.2) / 25.2(6.3) **Religion, n** Muslim 28 / 32 / 28 Hindu 9 / 11 / 5 Sikh 9 / 7 / 12 Christian 1 / 0 / 0 **Country of birth, n** Pakistan 23 / 26 / 24 India 13 / 13 / 9 East Africa 8 / 7 / 9 Bangladesh 3 / 4 / 2 England 0 / 0 / 1 **Primiparity, n** 17 / 18 / 18 **Vegetarian always (only during pregnancy), n** 5 (6) / 8 (8) / 4 (4) **Overcrowding in household, n** (>1.5 persons/room) 9 / 8 / 12 **Consanguinity among 1st cousins (among distant relatives), n** 9 (10) / 14 (4) / 13 (4) **Past history of LBW baby** 9 / 8 / 6 **Mean height [± SD], cm** 154.6 [4.4] / 156.3 [5.1] / 156.5 [5.8] **Mean weight [± SD], kg** 53.0 [9.1] / 54.6 [10.0] / 56.3 [10.6] **Mean MUAC [± SD], cm** 20.3 [1.9] / 20.4 [2.1] / 20.5 [1.9] **Group comparability at baseline** V group had fewer Hindus and more Sikhs, and had higher mean weight and height than others although these were not statistically significant	**Intervention** Participants received one of three supplements starting in 18th–20th week of pregnancy and continuing until the 38th week The EV group received the same iron and vitamin C in a carbonated glucose drink providing 273kcal (1.1MJ) energy The PEV group received iron, vitamin C and half the energy in a glucose drink along with the other half of the energy from protein in 26g chocolate flavoured skimmed milk powder – this provided the recommended daily intake for protein and energy during pregnancy (1.0 MJ with 10% from protein) Midwives delivered the supplements to the women's homes every 5 weeks; collecting empty bottles from the previous interval at the same time. A dietitian discussed the use of the supplement on clinic visits (every 5 weeks) and made one visit to the woman's home to check consumption **What controls got** The V group who served as controls received 3mg iron and 30mg vitamin C in 369mL of a carbonated water drink	**Statistical techniques** – Means, standard deviations, 2 tailed t-tests – Methods not clearly described **Data collection** – Routine obstetric examination – Anthropometry at study entry and at follow-up – 24 hour urine collection at 18, 23, 33, 38 weeks for urinary urea nitrogen, total nitrogen and sulphate – Venepuncture at 28, 33, 38 weeks for plasma albumin, calcium and alkaline ribonuclease activity – Dietary assessment every 5 weeks – method not described RESULTS **Average consumption of supplement throughout pregnancy** PEV / EV Kcal 34,000 / 33,000 Protein, g 892 **Maternal weight gain per week** – PEV group gained significantly more weight and fat per week between 18 and 28 weeks compared to V group mothers – PEV group gained more weight per week in the 3rd trimester compared to V group mothers but this was not statistically significant **Maternal triceps skinfold thickness** Weekly increment in triceps skinfold thickness was significantly higher ($p < 0.05$) in the PEV group compared to the V group **Maternal plasma albumin, mean [SD], g/L** PEV / V / p Week 28 35.8 [1.9] / 34.5 [2.3] / < 0.01 **Plasma ribonuclease activity, mean [SD], mcmol/L** Week 33 385 [73] / 433 [85] / < 0.02 **Mean crude birth weight** Similar in all three groups and not less than 3000g **Newborn triceps skinfold thickness** Greater ($p \approx 0.06$) in PEV compared to V group **Newborn MUAC** Significantly less ($p < 0.02$) in PEV group compared to V group **Mean placental weight** Approximately 600g in all three groups **Costs:** Not reported **Views:** Not reported	**Losses at late pregnancy follow-up interview** Total 11 PEV group 4 EV group 7 **Reasons for losses** Moved away 4 Abortions 2 Perinatal deaths 3 Twins 2	Data were analysed initially for all mothers offered the supplement, and then after excluding 28 women who failed to comply with the regimen +19 who had vaginal bleeding and/or hypertension. There were stated to be no significant differences in the results from both analyses; only the second set of results (intention-to-treat analysis not conducted) are presented in the paper Method of group allocation not reported **Strength of evidence** –

PEV = protein-energy-vitamin group; EV = energy-vitamin group; V = vitamin only or control group; MUAC = mid-upper-arm circumference; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 9: Nutritional supplementation RCT (Section 4.2: Nutrition supplement interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Viegas et al. 1982b UK **Research aim** To test the effectiveness of dietary protein energy supplementation on fetal growth and maternal nutritional state of Asian mothers at nutritional risk (defined as ≤ 20mm/week increment in triceps skinfold thickness) during the second trimester **Study design** Controlled trial **Method of group allocation** Paper states 'at random'; however, no details are provided **Unit of allocation** Individual women **Unit of analysis** Women Newborns **Sample size calculation** Not stated **Sample size achieved** 130 (45 nutritionally at risk; 85 not at risk) **Outcome measures** – Maternal weight – Maternal triceps, biceps, subscapular skinfold thickness – Maternal MUAC – Birth weight – Newborn mid upper arm circumference – Newborn triceps skinfold thickness	**Recruitment** Asian mothers booking for antenatal care at Sorrento Maternity Hospital, Birmingham, UK between 5 November 1979 and 11 June 1980 **Inclusion criteria** – Booking before 20 weeks pregnancy – Living within domiciliary midwives' areas 9 and 10 in the Birmingham Health Authority **Exclusion criteria** Not clear	**Age in years, mean [± SD]** Groups: PEV / EV / V n 44 / 43 / 41 24.2 [4.9] / 24.5 [5.4] / 23.4 [5.5] **Religion, n** Muslim 21 / 32 / 24 Hindu 12 / 4 / 4 Sikh 11 / 7 / 13 Christian 0 / 0 / 0 **Country of birth, n** Pakistan 16 / 26 / 21 India 17 / 7 / 10 East Africa 8 / 5 / 4 Bangladesh 3 / 4 / 2 England 0 / 1 / 4 **Primiparity, n** 19 / 18 / 18 **Vegetarian always (only during pregnancy), n** 8 (6) / 2 (3) / 2 (9) **Overcrowding in household, n** (> 1.5 persons/room) 10 / 12 / 13 **Consanguinity among 1st cousins (among distant relatives), n** 6 (3) / 18 (3) / 9 (2) **Past history of LBW baby** 3 / 4 / 2 **Mean height [± SD], cm** 155.8 [5.4] / 154.7 [6.9] / 155.8 [5.8] **Mean weight [± SD], kg** 55.7 [11.2] / 53.8 [8.9] / 56.1 [10.1] **Mean MUAC [± SD], cm** 20.9 [2.3] / 21.0 [2.1] / 21.1 [2.3]	**Intervention** Participants received one of three supplements from the 28th–38th week of pregnancy The EV group received a daily supplement of a multivitamin sachet plus glucose syrup providing 425kcal (1.8MJ) energy The PEV group received the same as the EV group except that 10% energy was provided by protein in the form of 40g of chocolate-flavoured powder Delivery of intervention was same as Viegas et al. 1982a, Table 8 **What controls got** The V group, who served as controls, received a multi-vitamin sachet	**Statistical techniques** Means and standard deviations calculated; methods not clearly described **Data collection** Same as Viegas et al. 1982a **RESULTS** **Average nutrition consumption 28–38 weeks** Energy, kcal / Protein, g PEV group 21,000 / 563 EV group 21,900 / – **Maternal weight gain g/week in 3rd trimester, mean ± SD** PEV / EV / V / p* At-risk group 480 / 304 / 312 / 0.08 Not at-risk 506 **Crude birth weight (n) mean, g [SD]** At-risk group (12) 3350 [470] / (15) 2900 [660] / (12) 3020 [260] / ≈ 0.05 Not at-risk (21) 2940 [440] / (23) 3080 [480] / (19) 3210 [420] / ≈ 0.06 **Thomson SD score (n) score [SD]** At-risk group (12) 0.16 [0.91] / (15) –0.12 [0.98] / (12) –0.56 [0.55] / < 0.05 Not at-risk (21) –0.52 [0.73] / (23) –0.36 [1.0] / (19) –0.16 [0.76] / ns Thomson SD score** is a standard deviation score using the Aberdeen reference data of birth weight for gestational age, sex, parity and maternal height from a sample of mothers in Aberdeen **Sorrento SD score (n) score [SD]** At-risk group (12) 0.68 [0.91] / (15) 0.26 [1.6] / (12) –0.23 [0.61] / < 0.02 Not at-risk (21) –0.21 [0.88] / (23) 0.0 [1.06] / (19) 0.28 [0.80] / ≈ 0.08 Sorrento SD score is a standard deviation score using an internal set of reference data of Sorrento mothers * denotes differences between PEV and V groups only ** Thomson AM, Billewicz WZ, Hytten FE (1968) The assessment of fetal growth. *Journal of Obstetrics and Gynaecology of the British Commonwealth* 75:903–16	**Total losses** 2 Both due to perinatal death	Data were analysed initially for all mothers offered the supplement, and then after excluding 12 women who failed to comply with the regimen + 14 who had vaginal bleeding and/or hypertension. There were stated to be no significant differences in the results from both analyses; only the second set of results (intention-to-treat analysis not conducted) are presented in the paper Group allocation was conducted at random; this has not been interpreted as formal random allocation, therefore the study is being reviewed as a controlled trial **Strength of evidence** –

PEV = protein-energy-vitamin group; EV = energy-vitamin group; V = vitamin only or control group; MUAC = mid-upper-arm circumference; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 9 (cont.): Nutritional supplementation RCT (Section 4.2: Nutrition supplement interventions)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
– Newborn MUAC – Mean placental weight **Dietary assessment** – 24 hour recall – Weighed diet periods from 3–7 days		**Group comparability at baseline** EV group had more Muslims from Pakistan and therefore more consanguineous marriages and fewer vegetarians		PEV / EV / V / p* **Gestational age (n) mean, weeks [SD]** At-risk group (12) 38.8 [1.3] / (15) 37.5 [2.5] / (12) 39.3 [1.2] / ns Not at-risk (21) 39.0 [1.5] / (23) 29.2 [1.2] / (19) 39.2 [1.0] / ns **Head circumference (n) mean, cm [SD]** At-risk group (12) 34.7 [1.0] / (15) 33.8 [1.9] / (12) 34.1 [1.0] / ns Not at-risk (21) 33.9 [1.2] / (23) 34.3 [1.4] / (19) 34.9 [1.2] / < 0.02 **Length at birth (n) mean, cm [SD]** At-risk group (12) 50.3 [2.2] / (15) 49.1 [4.1] / (12) 49.8 [1.8] / ns Not at-risk (21) 49.2 [2.8] / (23) 50.4 [3.2] / (19) 50.9 [2.3] / < 0.05 **Placental weight (n) mean, g [SD]** At-risk group (12) 641 [80] / (15) 601 [129] / (12) 555 [64] / < 0.02 Not at-risk (21) 582 [126] / (23) 605 [91] / (19) 603 [99] / ns * denotes differences between PEV and V groups only		

PEV = protein-energy-vitamin group; EV = energy-vitamin group; V = vitamin only or control group; MUAC = mid-upper-arm circumference; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 10: Nutrition education controlled trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection* Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Briley et al. 2002 USA **Research question** To evaluate the effectiveness of a prenatal nutrition curriculum on birth weights of infants born to African-American women enrolled in the WIC programme, and to measure the effect on participants' nutrient intake and weight gain Nutrition curriculum after Widga and Lewis 1999 **Study design** RCT **Method of randomisation** Not reported **Unit of allocation** Mother **Unit of analysis** Mother Newborn infant **Sample size calculation** Not reported **Sample size achieved** 27 **Outcome measures** – Birth weight – Dietary intake of vitamin B6, iron, folate, calcium, zinc – Maternal weight gain during pregnancy **Dietary assessment** 24 hour dietary recall	**Selection** Through the local county health department WIC programme, Lincoln, Nebraska Women volunteered to enter the study **Inclusion criteria** – ≤ 24 week gestation – Ethnic grouping African-American **Exclusion criteria** Not stated (implied in text – those having pre-existing health conditions, or being prescribed a diet for any reason)	15 women recruited to I group and 12 to C group – data presented only for 10 in each group who remained in the study I / C n: 10 / 10 **Pre-pregnancy BMI mean [SD]** 24.7 [3.4] / 23.2 [4.1] **Annual household income < $1500 n (%)** 8 (80) / 7 (70) **Living with family or friends n (%)** 9 (90) / 10 (100) **Age < 21 n (%)** 7 (70%) / 7 (70) **≤ high school education n (%)** 6 (60) / 9 (90) **Single mother n (%)** 8 (80) / 10 (100) **Unemployed n (%)** 6 (60) / 6 (60) **Group comparability at baseline** Yes	**Intervention** Delivered at home every week x 4 visits; then every month x 2 visits or until delivery. Key features – diet recall, nutrition advice, goal setting **Visit 1** – 24 hour diet recall – Anthropometric measurement – Prenatal questionnaire – Pre-pregnancy questionnaire – Two 24-hour diet recalls before next visit **Visit 2** – Food frequency questionnaire – Food guide pyramid – Recommended weight gain based on BMI – Weight gain graph (teaching aid) – Literature on pregnancy **Visit 3** – Discussion of calcium, iron, folate, fibre and protein sources – Discussion of dietary intake compared to Food Guide Pyramid – Goal setting – More literature **Visit 4** – Literature specific to teenage mothers – Meal planning – Shopping tips – Goal achievement discussed **Visit 5** – Reassessment of dietary intake – Strategies for managing weight gain **Visit 6** – Discussion of pre- and post-pregnancy diet analysis (computerised) – Special needs for breastfeeding **What controls got** Visits 1 and 5 same but no nutritional advice or goal setting	**Statistical techniques** – Chi-square tests were used to compare demographic characteristics of the two groups – Student's t-tests were used to compare energy and nutrient intakes – Paired t-tests were used to identify significant changes in intakes **Data collection methods** – 24 hour food recall using food models, measuring cups and spoons, food pictures; Food Processor Plus software (EHSA research 1995) used for analysis of dietary intake – Pre-pregnancy weight was self-reported – Height and weight using portable stadiometer and scale RESULTS I / C / p n: 10 / 10 **Birth weight mean, kg [SD]** 3.54 [0.4] / 3.06 [0.5] / < 0.05 **Maternal weight gain mean, kg [SD]** 11.9 [6.3] / 15.2 [5.1] **Daily nutrient intakes before intervention and after 5th home visit** **Energy intake, kcal [SD] (% RDA)** Before / After I group: 2219 [742] (89.5) / 2082 [612] (84) C group: 2458 [726] (99.1) / 2227 [871] (89.8) **Vitamin B 6, mg [SD] (% RDA)** I group: 1.6 [0.4] (84.2) / 2.3 [0.6] (121.1) C group: 1.7 [0.5] (89.5) / 1.7 [0.9] (89.5) **Calcium intake, mg [SD] (% RDA)** I group: 984 [385] (98.4) / 816 [200] (81.6) C group: 965 [554] (96.5) / 739 [424] (73.9) **Folate intake, µg [SD] (% RDA)** I group: 271 [69] (45.1) / 337 [120] (56.2) C group: 284 [138] (47.3) / 245 [155] (40.1) **Zinc intake, mg [SD] (% RDA)** I group: 10.2 [4.1] (67.7) / 10.7 [3.2] (71.1) C group: 11.0 [4.7] (73.4) / 10.5 [4.7] (70.2) **Iron intake, mg [SD] (% RDA)** I group: 12.6 [3.7] (42.3) / 19.4 [8.2] (64.5) / < 0.01 C group: 15.9 [6.7] (53.1) / 14.4 [6.1] (48.3) **Costs:** Not reported **Views:** Not reported	Intervention 5 Control 2 Women said they did not have time to meet with the nutritionist	Confounding factors such as parity, social support during index pregnancy, previous births, previous low birthweight were not taken into account **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 11: Nutrition counselling and supplementation controlled trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Doyle et al. 1992 UK **Research question** To study the associations between nutritional counselling and supplementation in the second and third trimester of pregnancy and birth outcomes **Study design** Controlled trial – one control and three test groups **Method of group allocation** On a rotating monthly basis all women were allocated to control group or one of three tests groups **Unit of allocation** Individual mother **Unit of analysis** Mother Newborn **Sample size calculation** Not reported **Sample size achieved** 1082 women **Outcome measures** – Birth weight – Maternal weight gain – Head circumference – Birth length – Length of gestation – Low birth weight **Dietary assessment method** 1 week food diary	**Selection** From Salvation Army Mothers Hospital, East London **Inclusion criteria** – Pregnant women in the 1st trimester of pregnancy at the time of recruitment – Caucasian or African-Caribbean origin **Exclusion criteria** Not reported	Group A / Group B n: 266 / 633 **Age mean, y (SEM)** 25.4 (0.31) / 24.2 (0.19) **Maternal body weight, kg (SEM)** 58.7 (0.66) / 60.1 (0.42) **Height in cm (SEM)** 162 (0.36) / 162 (0.25) **Mean BMI (SEM)** 22.3 (0.24) / 22.9 (0.16) **Marital status** Married (%) 51 / 54 Single (%) 49 / 46 **Parity** Parity 0 (%) 52 / 52 Parity 1 (%) 31 / 32 Parity 2 (%) 10 / 11 Parity 3–6 (%) 7 / 5 **Smoking status** Non-smokers (%) 65 / 70 Smoker < 10 cigarettes/day (%) 22 / 19 Smoker ≥ 10/day (%) 14 / 11 **Group comparability** Group B mothers were on average 1.4 kg heavier with BMI ~ 0.5kg/m^2 higher before the counselling began	**Intervention** Three test groups B1, B2, B3 Group B1 got nutrition counselling from a dietitian every 3 weeks during 2nd and 3rd trimester; feedback of report based on food diary analysis Group B2 got counselling + vitamin-mineral supplement Group B3 got counselling + vitamin-mineral supplement + linoleic acid supplement in the form of oil/margarine (Supplements were intended to be shared with other family members) **What controls got** Group A – no counselling, no supplements	**Statistical techniques** Mann-Whitney U test used to test significance of differences between groups **Data collection methods** – Food diary – 1 week (Group B only) – Dietary recall discussion if not willing to keep a food diary RESULTS OF COUNSELLING Group B (Intervention) / Group A (Control) / p n: 633 / 266 LBW n (%): 34 (5.4) / 20 (7.5) / 0.216 Birth weight < 3000g n (%): 182 (28.8) / 92 (34.6) / 0.083 Head circumference, mean, cm (SEM): 34.3 (0.06) / 34.1 (0.09) / 0.124 Length of newborn at birth, mean, cm (SEM): 51.1 (0.12) / 51.0 (0.20) / 0.499 Length of gestation, mean, days (SEM): 275 (0.43) / 275 (0.69) / 0.861 Maternal weight gain, kg (SEM): 12.3 (0.18) / 11.9 (0.30) / 0.22 Mean birth weight,* g (SEM): 3284 (19.7) / 3192 (30.20) / 0.010 * Unadjusted for maternal body weight before registration, difference = 92g When adjusted for maternal body weight before registration, difference = 78g at p < 0.027 RESULTS OF SUPPLEMENTATION DURING SECOND AND THIRD TRIMESTERS B1 / B2 / B3 / A n: 17 / 211 / 05 / 266 LBW < 2500g %: 4.7 / 3.8 / 6.9 / 7.5 Mean birth weight,* g (SEM): 3266 (33.6) / 3317 (33.0) / 3268 (35.8) / 3192 (30.2) Length of gestation,* days (SEM): 274 (0.72) / 276 (0.71) / 274 (0.8) / 275 (0.69) Maternal weight gain,* kg (SEM): 12.2 (0.33) / 12.0 (0.30) / 12.7 (0.32) / 11.9 (0.30) *No significant differences; results same if only mothers completing food diaries (n = 419) included in analysis	**Lost or dropped out from control group** Total = 60 (18.4%) Reasons – moved away, miscarried, terminated, stillbirth, multiple birth **Lost or dropped out of intervention groups** Total =123 (16%) Reasons – seen by dietitian < 3 times, moved away, miscarried, terminated pregnancy, stillbirth, multiple birth	Strength of evidence +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; SEM = standard error of mean; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 12: Nutrition education and counselling before-after study (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Gray-Donald et al. 2000 Canada **Research question** To evaluate the effectiveness of a nutrition education and counselling intervention to reduce maternal weight gain and prevent gestational diabetes **Study design** Before-after study **Method** Cross-sectional study of pregnant women before and after the intervention **Unit of allocation** Individual woman **Unit of analysis** Woman, newborn **Sample size calculation** Calculated for 80% power to detect a difference of 215g in birth weight, energy intake of 1396kJ, plasma glucose level of 0.74mmol/L, rate of weight gain of 0.01kg/week and postpartum weight retention at 6 weeks postpartum of 1.9kg **Sample size achieved** 219 **Outcome measures** – Maternal weight gain – Plasma glucose – Birth weight – Rate of caesarean section **Dietary assessment** 24 hour recall	**Selection** Cree women receiving prenatal services in the communities in Chisasibi, Wemindji, Waswanipi and Mistissini in Northern Quebec between July 1995 and January 1997 were eligible **Inclusion** criteria – < 26 weeks gestation – Receiving prenatal services – Belonging to one of four indigenous communities **Exclusion criteria** Women with pre-gestational diabetes	I / C n 112 / 107 **Mean age in year [SD]** 24.3 [6.29] / 23.8 [5.86] **Gestational duration at entry in weeks mean [SD]** 17.1 [7.06] / 18.5 [6.92] **Pre-pregnancy weight in kg [SD]** 81.0 [19.46]* / 78.9 [17.54]** **Mean BMI kg/cm^2 [SD]** 30.8 [6.85]* / 29.6 [6.5]** * Based on 101 women ** Based on 98 women **Parity 0 (n)** (35) 31% / (40)37% **Parity 1 (n)** (31) 28% / (28) 26% **Parity 2–4 (n)** (38) 34% / (37) 35% **Parity ≥ 4 (n)** (8) 7% / (2) 2% **Smokers (n)** (58) 52% / (45) 42% **Group comparability** Differences in age, pre-pregnant weight, gestational age at recruitment, BMI and intakes at 27 weeks pregnancy between the groups were not significant	**Intervention** The theoretical basis for intervention was Bandura's social learning theory. It was delivered by 2 research nutritionists who were living in the community over both the control and intervention periods. Dietary advice was related to intake of dairy products (increase), fruit and vegetables (increase), soft drinks (decrease), and french fries (decrease), and staying within the recommended weight gain in pregnancy. This was done through local radio broadcasts, distribution of pamphlets, cooking demonstrations, supermarket tours and individual counselling. Modelling, skills training, contracting and self-monitoring strategies were used **What controls got** It is not clear from the paper. Implied that they would have got routine prenatal care (not described)	**Statistical techniques** – Independent t-tests used to compare mean nutrient intakes, birth weight, birth weight ratio, gestational age, rate of weight gain, glycaemic level and postpartum weight retention – Log transformation was used to normalise pre-gravid weight, BMI, postpartum weight **Data collection methods** – 24-hour dietary recall once between 24–30 weeks pregnancy and then at 6 weeks postpartum. Food Processor I version 5.3 and Canadian Nutrient Database File (EHSA research, Salem) used to obtain nutrient intake – Questionnaire for demographic characteristics, smoking and physical activity – Infant birth weights from medical records – Gestational age by ultrasonography at 16–20 weeks – Pre-gravid weight from recall or 1st prenatal visit – Physical activity: self-report RESULTS **Mean no [SD] of individual counselling sessions** = 4.03 [1.68] I / C / p **Birth weight (n) mean, g [SD]** (106) 3686 [686] / (103) 3741 [523] / ns **Birth weight > 4000g (n) %** (106) 34.9 / (103) 30.1 / ns **Rate of low birth weight < 2500g (n) %** (106) 2.83 / (103) 1.94 / ns **Birth weight ratio [SD]** (106) 1.15 [0.16] / (103) 1.15 [0.18] / ns Birth weight ratio = infants weight at delivery divided by reference weight at gestational age Cree infants in both groups were on average 15% heavier than non-native infants after adjusting for gestational age **Gestational age at delivery (n) mean, weeks [SD]** (106) 39.53 [3.42] / (103) 39.56 [1.87] / ns **Plasma glucose (n) mean in mmol/L [SD]** (97) 7.43 [2.10] / (87) 7.21[2.09] / ns	Controls 2 Intervention group 3 **Reasons** miscarriage	Strength of evidence +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 12 (cont.): Nutrition education and counselling before-after study (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
				I / C / p Rate of caesarean section (n) % I: (106) 14.15; C: (103) 12.62; p: ns Daily dietary intake of folate at 6 weeks postpartum mean, µg [SD] I: 304 [19.9]; C: 373 [27.2]; p: 0.035 Maternal weight gain/week in women with BMI ≤ 29 kg/m^2 (n) mean, kg [SD] I: (51) 0.62 [0.27]; C: (49) 0.63 [0.32]; p: ns Maternal weight gain/ week in women with BMI >29 kg/m2 (n) mean, kg [SD] I: (53) 0.44 [0.24]; C: (47) 0.44 [0.30]; p: ns Breastfeeding rates at 6 weeks postpartum I: 87%; C: 83%; p: ns Mean dietary intake of all nutrients at 6 weeks postpartum were similar except for a positive difference ($p < 0.35$) in folate intake in favour of the intervention group Views: Women welcomed the presence of nutrition experts in the community; women perceived that being plump was desirable Costs: Not reported		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 13: Nutrition education intervention RCT (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Hunt et al. 1976 USA **Research aim** To determine if food habits and biochemical indices of nutritional status can be improved with nutrition education in a sample of pregnant women of Mexican descent **Study design** RCT **Method of randomisation** Not reported **Unit of allocation** Individual women **Unit of analysis** Mother Infant **Sample size calculation** Not reported **Sample size achieved** 344 randomised **Outcome measures** – Nutrient intake – Nutrition knowledge – Haemoglobin – Haematocrit – Serum protein – Serum iron – Serum folate – RBC folate – Plasma carotene **Dietary assessment** 24 hour recall	**Selection** Spanish-speaking women attending two Los Angeles county prenatal clinics from 1972–1974 **Inclusion criteria** – < 21 weeks pregnant at first prenatal clinic visit – Self-planning and preparation of meals **Exclusion criteria** – Heart disease – Diabetes	**Migrants from Mexico** 92% **Spent majority of birth to teen years in the US** 3% I C n 173 171 **Number of years in LA county mean [SD]** 4 [3] 3 [3] **Age in years mean [SD]** 25 [5] 25 [6] **No. of years spent in education mean [SD]** 6 [3] 6 [3] **No. of children in household mean [SD]** 1.7 [1.9] 1.7 [2.2] **Pre-pregnancy weight (n) mean, kg [SD]** (158) 56.7 [23] (150) 57.1 [19] **Monthly income in USD (n) mean [SD]** (169) 361 [128] (163) 347 [119] Over half the diets recorded from participants were below 2/3rds of the RDA for ≥ 3 nutrients **Group comparability at baseline** Significant for differences not reported	**Intervention** In addition to routine prenatal care, five nutrition education classes were delivered in Spanish by a nutritionist about food purchases, storage and preparation of nutritious meals. The classes were delivered in the study period, all at the prenatal clinic + same as the control group **What controls got** Routine prenatal care including doctor/nurse examination; dietary information; multi-vitamin capsule; iron supplement; no nutrition classes	**Statistical techniques** – t-tests – Chi-square tests – McNemar's formula for determining significance of changes with groups in the number of women deficient of a micronutrient **Data collection methods** – 24 hour dietary recall using food models, glasses and spoons of varying sizes, was conducted at entry and in the 35th week of pregnancy. Analysis of results were done on computer (software not reported) – Nutrition quiz at beginning and end of study – Blood samples for biochemical indices **RESULTS** **Nutrition quiz correct scores before and after intervention** Before / After I group: 41% / 69% C group: 42% / 47% p: ns / < 0.005 **Change in dietary intake after intervention, mean [SD]** I / p / C / p n: 147 / / 132 / Calories, kcal: 133 [779] / < 0.05 / 127 [602] / < 0.02 Carbohydrate, g: 23 [99] / < 0.01 / 18 [84] / < 0.02 Fat, g: 2 [45] / ns / 5 [37] / ns Protein, g: 8 [31] / < 0.01 / 3 [28] / ns Iron, mg: 0.7 [5.6] / ns / –0.1 [4.3] / ns Calcium, mg: 193 [497] / < 0.01 / 117 [464] / < 0.01 There was a statistically significant difference in the percentages of intervention group participants with less than 2/3rd the RDA for calcium, ascorbic acid and riboflavin after the intervention **Micronutrient status at end of study, mean** I / p / C / p n: 117 / / 98 / Haemoglobin, g/dl: 13.1 / ns / 13.1 / ns Haematocrit, %: 36.9 / ns / 37.3 / ns Serum protein, g/dl: 7.3 / ns / 7.4 / ns Serum iron, µg/dl: 90.7 / ns / 90.9* / ns Serum folic acid, ng/dl: 8.9** / < 0.01 / 10.1 / < 0.01 RBC folate, ng/mL: 335 / < 0.01 / 328 / ns * n = 96; ** n = 118 **Costs:** Not reported **Views:** not reported	Total: 65 (24 due to premature birth; 16 because they delivered after the study; 14 moved out of the area; 8 could not be traced; 3 had abortion/ miscarriage) Not reported by group	Strength of evidence +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 14: Nutrition education intervention cluster randomised trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Kafatos et al. 1989 Greece **Research question** To assess the effects of nutrition education in improving the dietary plan of women and to evaluate the impact of nutrition counselling on maternal weight gain and pregnancy outcome **Study design** Group randomised controlled trial **Method of group allocation** – Cluster randomisation – 10 clinics randomised to intervention group – 10 clinics to control group **Unit of allocation** Women attending clinics (cluster) **Unit of analysis** – Woman – Baby **Sample size calculation** Not reported **Sample size achieved** 568 **Outcome measures** – Birth weight – Premature birth – Maternal weight gain – Haemoglobin in mmol/L – Anaemia (< 1.7mmol/L) – Serum iron deficiency (< 10.74mcmol/L)	**Selection** All pregnant women attending clinics serving the whole population in the county Florina, Greece **Inclusion criteria** Not reported **Exclusion criteria** Not reported	I / C n 296 / 263 **Maternal age, (n) mean in years [mean ± SE]** (296) 23.1 [0.31] (263) 22.9 [0.31] **Maternal age at first pregnancy, (n) mean in y [mean ± SE]** (296) 20.35 [0.23] (263) 20.27 [0.23] **Maternal height (n) mean in cm [mean ± SE]** (294) 157.8 ± 0.38 (259) 160 ± 0.33 **Initial weight, (n) mean in kg [mean ± SE]** (281) 57.6 [4.8] (254) 58.2 [5.1] **Inter-pregnancy interval, in years (n) mean [SD]** (180) 2.46 [1.42] (146) 2.52 [1.44] **Parity** n 296 263 Primiparae 38.5% 43.1% 2–3 pregnancies 47.6% 44.7% Multiparae 13.9% 12.2% **Previous history of LBW (n) %** (21) 11.5% (10) 6.7% **Low socio-economic status (n) %** (214) 72.5 (180) 68.4 Gestational age at enrolment was ~ 16+ weeks – no significant difference between groups **Group comparability at baseline** No significant differences in groups at baseline except for a significant difference ($p < 0.01$) in height	**Intervention** – Provision of written and oral information / instruction on nutrition for improving health of mother and baby – Practical advice about improving quality of diet and increasing consumption of foods rich in nutritional value – Delivered at home every 2 weeks by a trained nurse from 21–27 weeks pregnancy until delivery **What controls got** Not reported	**Statistical techniques** – Analysis of co-variance for detecting significant differences in nutritional intake, haemoglobin and serum vitamin levels – Analysis of co-variance for changes in biochemical indicators, two-way analysis of co-variance for gestational age at enrolment – One-way analysis of variance and co-variance for assessment of birth weight – Chi-square or Fisher's exact tests for comparisons of anaemia – McNemar's tests for early vs late comparisons **Data collection methods** – 24 hour dietary recall initially and every 4 weeks; USDA food composition database used for converting food intake into nutrient intake – Food weighing inventory **RESULTS** I / C / p **Rate of low birth weight (< 2500g), n (%)** 291 (4.5) 256 (3.9) ns **Birth weight, (n) mean, g [SD]** (272) 3391 [26.34] (245) 3376 [31.86] ns **Gestational age at birth (n) mean, w [mean ± SE]** (265) 39.6 [0.01] (244) 39.7 [0.14] ns **Rate of small-for-gestational age babies, n (%)** 287 (6.0) 250 (6.0) ns **Rate of premature birth, n (%)** 294 (3.7) 253 (8.3) < 0.04 **Rate of neonatal mortality (< 27 days) n/N** 6/285 5/256 **Maternal weight gain > 37 weeks in kg (n) mean, kg [SD]** (176) 11.3 [0.31] (97) 10.3 [0.39] < 0.05 **Haemoglobin, (n) mean, mmol/L [SD]** Before / After I (232) 1.81 [0.01] (232) 1.83 [0.03] C (133) 1.87 [0.02] (133) 1.88 [0.03] p < 0.02	Not reported	Mean birth weight was not adjusted for gestational age at birth **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 14 (cont.): Nutrition education intervention cluster randomised trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence

				Anaemia (Hb < 1.7 mmol/L)
				  Before / After
				I 25.9% / 25.4%
				C 20.3% / 22.6%
				p ns / ns
				
				Serum iron (n) mean, mcmol/L [SD]
				  Before / After
				I (118) 21.08 [1.42] / (118) 20.61 [1.49]
				C (61) 21.88 [0.87] / (61) 24.1 [2.04]
				p ns / ns
				
				Iron deficiency (< 10.74 mcmol/L)
				  Before / After
				I 5.9% / 11%
				C 4.9% / 3.3%
				p ns / ns
				
				Maternal energy intake significantly higher in intervention group throughout pregnancy; at 37 weeks this reached statistical significance $p < 0.0001$
				
				Costs: Not reported
				
				Views: Not reported		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 15: Nutrition education controlled trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Long et al. 2002 USA **Research question** What is the impact of a nutrition education curriculum for pregnant and parenting teens on pregnancy outcomes, nutrition knowledge and diet quality? **Study design** Controlled trial **Method of group allocation** Not reported **Unit of allocation** Individual woman **Unit of analysis** Woman Newborn infant **Sample size calculation** Not reported **Sample size achieved** 301 **Outcome measures** – Mean maternal weight gain – Apgar scores at birth and 5 minutes – Mean infant birth weight – Incidence of low birth weight – Rates of caesarean section – Nutrition knowledge **Dietary assessment** 24 hour recall	**Selection** – Pregnant teenagers participating in the Great Beginnings programme and WIC in Durham, New Hampshire, USA – Non-pregnant teenagers participating in the Great Beginnings programme – Pregnant teens in WIC programme but not exposed to the programme – Non-pregnant teenage high school students not participating in the programme or in WIC **Inclusion criteria** See above **Exclusion criteria** Not stated	I / C1 / C2 / C3 n = 136 / 65 / 50 / 50 Subject characteristics not reported in paper **Group comparability** No details available to comment on comparability	**Intervention** The Great Beginnings curriculum (six lessons in nutrition through presentations, discussions, and hands-on activities – based on teenagers' identified needs) + usual WIC interventions **What controls got** – C1 (n = 65): pregnant adolescents received WIC inputs only – C2 (n = 50): non-pregnant high school students who were exposed to the Great Beginnings programme but not WIC – C3 (n = 50): non-pregnant high schoolers with no exposure to Great Beginnings or WIC	**Statistical techniques** – Descriptive statistics for demographic variables – Analysis of variance for nutrition knowledge test before and after intervention, diet quality and birth outcomes – Nutritionist III nutrient analysis program version 6.0 1988 for analysis of 24 hour diet recall – One-tailed t-test for differences in incidence of low birth weight between I and C1 **Data collection methods** – 24 hour dietary recall initially and after 6 weeks – Birth records for I and C1 groups – Entry and exit knowledge tests **RESULTS** I / C1 / p n = 136 / 65 **Rate of low birthweight %** 6.6 / 12.3 / 0.05 **Birth weight mean, g [SD]** 3328.60 [588.07] / 3206.18 [616.81] / 0.178 **Maternal weight gain mean, kg [SD]** 16.022 [5.76] / 14.99 [6.43] / 0.261 **Apgar scores mean [SD]** 7.76 [1.62] / 7.73 [1.89] **Rate of caesarean section** 13% / 6% **Nutrition knowledge** Before / After I (n = 136) 23.2 / 31.04 C1 (n = 65) 20.7 / 24.45 C2 (n = 50) 20.6 / 20.26 C3 (n = 50) 20.3 / 20.20 Both groups receiving the Great Beginnings curriculum (I and C2) increased their nutrition knowledge scores; those who were pregnant (I and C1 groups) achieved higher scores than those who were not pregnant (C2 and C3) **Costs:** Not reported **Views:** Not reported	None reported	No information given in the paper on how the teenagers were recruited or selected, losses, lack of data comparing characteristics of intervention and control group **Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 16: Nutrition counselling RCT (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Sweeney et al. 1985 USA **Research question** To identify the effects of individual prescriptions for protein and calories during pregnancy on maternal and infant outcomes **Study design** RCT **Method of group allocation** Biased coin methodology after stratification by pre-pregnancy weight and weight gain in the first 20 weeks of pregnancy **Unit of allocation** Mother **Unit of analysis** Mother Newborn **Sample size calculation** Not reported **Sample size achieved** 47 **Outcome measures** – Protein and caloric intake – Compliance with prescription – Maternal weight gain – Birthweight **Dietary assessment** 7 day dietary history	**Selection** At a regional tertiary care centre in Salt Lake City **Inclusion criteria** – Registration for prenatal care < 20 weeks pregnancy – Due to delivery in one of two designated 10 week periods – Fluency in English – Free of medical conditions **Exclusion criteria** Private patients and teen clinic patients not included	Ethnicity white 100% Married 85% Age range 17–34 Mean age 23.1 Annual household income < $10,000 62% Occupation home-maker 70% Pre-pregnant weight 41–113kg Maternal height 152–180cm WIC participants 33% Number of completed years of education 9–18 Mean years of completed education 12.7 **Group comparability** Groups were comparable at baseline for all characteristics including smoking, alcohol intake, anthropometric measurements and obstetric experience	**Intervention** Nutritional assessment + protein and calorie prescription based on body weight, build, activity level and current nutritional status; counselling to take the prescribed nutrition each 24 hours through 10 minute video tape based on Higgins' counselling principles; face-to-face contact (total of 4–8 contacts) **What controls got** Prescription calculated but not given to the women; no counselling, but were allowed to ask questions; a motivational film 'Inside my Mom'	**Statistical techniques** – One-tailed test for differences in protein/energy intake – Two-tailed tests for differences in maternal weight gain and infant birth weight – Pearson correlation for association between increase in intakes and placental weight gain **Data collection methods** 7 day dietary history from recall of intake and of food purchases RESULTS **Adjusted prescription for protein mean [SD] in g** 108 [23.2] **Adjusted prescription for calories mean [SD] in kcal** 2994 [304.1] Mean number of contacts between researcher and participant = 6.2 over 8-21 weeks after the first contact during the index pregnancy I / C / p n: 18 / 25 **Protein intake/day mean, g [SD]** 91.6 [18.3] / 80.8 [21.9] / = 0.04 **Caloric intake/day mean, kg [SD]** 2562 [423.9] / 2373 [538.0] / ns **No. of participants taking ≥ 85% of the prescription (adequate intake group)** 10 / 8 **No. of participants taking < 85% of the prescription (inadequate intake group)** 12 / 13 **Birthweight (n) mean, g [SD]** Adequate group (n = 17) 3411.8 [363] Inadequate group (n = 8) 2921.3 [340] p < 0.04 **Total maternal weight gain (n) mean, kg** Adequate group (n=17) 16.09 Inadequate group (n =8) 11.13 p < 0.005 Gaining 4.54kg in the first 20 weeks of pregnancy may predict a further gain to at least 9kg (p < 0.0001)	– Twin pregnancy 2 – Delivered < 22 weeks gestation 1 – Incomplete data 1	**Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 17: Nutrition education and counselling controlled trial (Section 4.3: Nutrition education/counselling studies)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Widga and Lewis 1999 **USA** **Research question** To assess the effectiveness of a prenatal dietary intervention in improving dietary intake, maternal weight at the time of delivery and infant birth weight **Study design** Controlled trial **Method of group allocation** First two attendees at a prenatal clinic assigned to intervention group; third to control group **Unit of allocation** Woman **Unit of analysis** Woman Newborn **Sample size calculation** Not reported **Sample size achieved** 81 [I=55; C=26] **Outcome measures** – Infant birth weight – Micronutrient intakes – Energy intakes – Mother's weight at delivery **Dietary assessment** 24 hour recall	**Selection** From local county health department **Inclusion criteria** – Low income – < 24 week gestation at entry **Exclusion criteria** Not reported	81 were recruited, baseline characteristics were available for 66 participants I / C / p n: 40 / 26 **Age in years mean [SD]** 22 [4.4] / 22.8 [3.6] **Single mothers** 70% / 85% **Minority ethnic group** 18% / 42% / < 0.05 **Only high school education** 53% / 44%* **> High school education** 40% / 24%* * n = 25 **Group comparability** At baseline all characteristics were similar except for ethnic grouping	**Intervention** – Nutritionist delivered intervention at participant's home every week for 4 weeks, followed by every month for a minimum of 2 months or until end of pregnancy – Topics covered were basic nutrition, weight gain, special nutrients, menu planning, shopping tips, harmful substances, continued good nutrition – Materials used: The Food Guide Pyramid – A significant person was identified as part of the intervention to provide support with implementation with the advice – Weight measurement* – Food frequency questionnaire* – 24 hour dietary recall* – 2 day food record* – Nutrition education and counselling* – Individual goal setting* * At every visit **What controls got** Not reported	**Statistical techniques** – Paired t-tests using SAS V6 for comparing nutrient intake before and after intervention – Correlation analysis for identifying variables connected with birth weight – t-tests for comparing birth weights of babies in intervention and control groups – Chi-square to compare categoric variables **Data collection methods** – 24 hour food recall using pictures, household utensils – 2 day food records – Food frequency pattern after food guide pyramid. Food Processor software used to convert dietary intake to nutrient intake RESULTS I / C / p **Birth weight mean [SD], g** 3381 [554] / 3459 [502] / ns **Intake [SD] % of RDA, mean in intervention group** Before / After / p Energy, kcal: 2269 [587] 91 / 2431 [651] 98 / < 0.05 Folate, mcg: 345 [153] 86 / 412 [216] 103 / < 0.01 Iron, mg: 17.5 [8.8] 58 / 21.2 [10] 71 Calcium, mg: 1175 [455] 98 / 1299 [491] 108 / < 0.01 Zinc, mg: 13.6 [4.8] 91 / 14.7 [5.2] 98 / < 0.01 Vitamin B6, mg: 2.1 [0.7] 96 / 2.5 [1.0] 114 / < 0.01 **Gestational age at birth, weeks (n) mean [SD]** I / C / p (39) 39.9 [1.2] / (16) 39.5 [1.1] / ns **Maternal weight gain, mean, kg [SD]** 15 [5.5] / 14.1 [5.8] / ns **Costs:** Not reported **Views:** Not reported	**I group:** – Premature delivery, dropped from the analysis 5 – Not included in analysis because they did not complete six visits 10 **C group:** – Moved out of the area 5 – Dropped out due to time commitments 2 – Dropped out because of family problems 3	**Strength of evidence** –

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 18: Complex health and social care intervention RCT (Section 4.4: Complex health and social care interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Graham et al. 1992 USA **Research question** Can screening for poor pregnancy outcomes and intervention with high-risk, inner-city black women improve pregnancy outcomes? Sub-set of questions: – Do high-risk women receiving a home based intervention differ in rates of LBW from those who do not? – Does home intervention affect use of prenatal care? – Does prenatal care affect the rate of low birth weight? – Can a screening tool that takes account of social, psychological and medical condition predict which pregnant woman will deliver a LBW baby better than one using medical information? **Study design** RCT **Method of randomisation** Large table of random numbers; odd vs even digits **Unit of allocation** Individual woman **Unit of analysis** Newborn **Sample size calculation** 154 in intervention and control groups to detect a difference of 15% in rates of low birth weight with a power of 0.80 and a directional type error of 0.05 **Sample size achieved** 145 [I =87; C = 58] **Outcome measures** – Low birth weight – No. of prenatal visit – Efficacy of screening **Dietary assessment** Not reported	**Selection** Women attending the prenatal clinic of MacDonald hospital for women (University Hospitals of Cleveland, Ohio) between May 1987 and May 1988 **Inclusion criteria (absolute)** – 17–28 weeks gestation – Low/marginal (< 18) family function score on either Family Apgar; or low/marginal (< 63) in the Modified Index of Family Relationships – ≥ 1 stressful life event during pregnancy before registration **Inclusion criteria (additional/ optional)** – Smoker – Low maternal weight/height ratio – > 27 years of age – Previous premature baby **Exclusion criteria** – > 28 weeks gestation – Living outside a 5 mile radius from the hospital	**Mean maternal age in years**:24 Age 14–19 21% ≥ 35 4% **Primiparous women** 38% **Married** 11% **Used Medicaid** 84% **Mean duration of pregnancy at registration in weeks** 18.5 **% of women on Medicaid** I C p 93.1 74.5 < 0.01 **Group comparability at baseline** Medicaid cover, which was the only variable reported by group, was significantly different; other characteristics were not reported by group	**Intervention (in addition to routine care)** 'Peer' type home visitors especially trained to deliver the intervention provided the following services at the participant's home: – Psychosocial support to patient and encouragement to the family to increase support, to be present for the home visit, clinic visit, maternity classes and delivery – Efforts to reduce family stress by referral to community services and acting as a family advocate when needed – Information about health risks of smoking and alcohol consumption, referral to treatment groups for cessation – Increased awareness of community resources – Nutrition education and information about prenatal care and childbirth – A small gift (example: baby rattle) at each visit **What controls got** Routine obstetric care provided at prenatal clinic	**Statistical techniques** – Chi-square tests were used to test for differences in LBW rates between I and C groups, adequacy of clinic visits, cross-validation of screening tools – Student t-tests were used for differences between I and C groups in time of registration, and two measures of family functioning – Discriminant analysis for predictors of LBW **Data collection methods** – Screening tool (questionnaire) containing medical and psychosocial questions – Hospital charts **RESULTS** **Rates of LBW (n) [no. for whom data were not available] %** p C group* (53) [5] 7.5 I group (received some home visits) (62) [1] 12.9 0.51 I group (received 4 home visits) (52) [–] 7.7 0.98 * Excludes one intrauterine death **Actual vs expected number of prenatal clinic visits (n) [no. for whom clinic data were incomplete] mean ratio** C group (48) [10] 0.93 I group (received some home visits) (57) [6] 1.12 0.029 I group (received 4 home visits) (49) [3] 1.17 0.007 **Rate of LBW by adequacy of prenatal clinic visits** Adequate no. of prenatal visits 7.1%; Inadequate no. of prenatal visits 8.8%; 0.77 **Strength of screening tool to detect LBW** Women at high risk for LBW (n = 166, missing = 29); Women at low risk for LBW (n = 744, missing = 278) **Actual rate of LBW** 9% 11% 0.43 **Views:** Not reported **Costs:** Not reported	**Lost or dropped out from control group** 0 **Lost or dropped out of intervention groups** 24 – Refused intervention 7 – Unable to contact 11 – Transferred care 5 – Miscarried 1	Four home visits are probably not sufficient to address family dysfunction and stress There was no relationship between improved prenatal clinic attendance and reduction in low birth weight The disconnect between home visitor and clinic staff appears to have been a barrier to optimal patient care (there was no exchange between home visitors and clinic staff about the women, eg smoking during pregnancy etc) **Strength of evidence** +

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 19: Complex health and social care intervention RCT (Section 4.4: Complex health and social care interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
Olds et al. 1986 USA **Research aim** To evaluate a comprehensive programme of prenatal and postpartum nurse home visitation **Target group** Black-American, young, single mothers **Study design** RCT **Method of randomisation** Women drew their treatment assignment from a pack of cards – the packs were specific for race and marital status at intake, for area of residence and ethnicity, thus enabling stratification of the whole sample **Unit of allocation** Individual mother **Unit of analysis** Mother Newborn **Sample size calculation** Not reported **Sample size enrolled** 400 **Outcome measures** – Use of services – Support persons behaviour – Obstetric conditions such as bleeding, spotting – Health habits like smoking, alcohol consumption – Birth weight	**Selection** From health department antepartum clinic and offices of private obstetricians, Planned Parenthood, public schools and other health and human service agencies in a small semi-rural county in the Appalachian region of New York State (rated worst in terms of economic conditions, high rates of infant mortality and child abuse) between April 1978 and September 1980 **Inclusion criteria** – No previous live births – Age < 19 –Single parent – Low socio-economic status – < 25 weeks gestation **Exclusion criteria** ≥ 25 weeks gestation To reduce risk of programme being stigmatised as being exclusively for the poor, any woman who asked to participate and was bearing a first child was enrolled in the study	Number enrolled to study = 400; data tabulated for 354 participants Groups 1&2 / Groups 3&4 / Difference & 95% CI n 165 / 189 **Mean maternal age in years** 19.57 / 19.53 / 0.04 ± 0.66 **No of weeks pregnant at registration** 17.12 / 17.44 / –0.32 ±1.01 **Completed education in years** 11.21 / 11.34 / –0.13 ± 0.32 **Proportion of households in social class IV and V** 0.61 / 0.61 / 0.00 ± 0.10 **Proportion married** 0.43 / 0.41 / 0.02 ± 0.10 **Proportion at low risk** 0.17 / 0.14 / 0.03 ± 0.08 **Pre-pregnant weight in kg** 59.08 / 59.65 / –1.24 ± 6.20 **No. of cigarettes smoked/day** 6.94 / 7.65 / –0.71 ± 1.97 **Adequacy diet (average % RDA of 12 nutrients** 72.46 / 69.34 / 3.12 ± 3.77 **No. of kin/helpers** 3.22 / 2.86 / 0.36 ± 0.41* * Significant difference (p < 0.10) in no. of kin and confidence that someone would accompany them to labour in nurse-visited group. No significant differences in other characteristics	**Intervention** Group 1 (control group) (n = 90) got health and developmental screening for the child at age 1 and 2 years Group 2 (n = 94) got health and developmental screening for the child at age 1 and 2 years + free transportation (through a contract with a local taxi service) to regular prenatal and well-child clinics Group 3 (n = 100) got health and developmental screening for the child at age 1 and 2 years + free transportation to regular prenatal and well-child clinics + prenatal nurse home visits Group 4 (n = 116) got health and developmental screening for the child at age 1 and 2 years + free transportation to regular prenatal and well-child clinics + prenatal home visitation + nurse home visits during child's first two years	**Statistical techniques** A core statistical 2 x 2 x 2 x 2 factorial design model was used consisting of treatment group (Groups 1 + 2 vs 3 + 4) x cigarette smoking status (0–4/day vs ≥ 5/day) x maternal age (< vs > 17 years) x sex of baby (male vs female) thus giving 16 subclasses; this model was extended to include a repeated measures structure for dependent variables measured at 1st and 2nd interview **Data collection** – Interview at entry to study and in 32nd week gestation – Data was extracted from medical records – Observational data collected in labour suite – 24 hour diet records and 24 hour diet recalls – Blood samples were taken for serum cotinine levels – General and logistic linear modelling of variables and co-variates RESULTS Groups 3&4 Nurse-visited / Groups 1&2 Controls / Diff & 95% CI / p **MBW of babies born to all women, adjusted (n) mean g** (166) 3285 / (142) 3262 / 23 ± 134 **MBW of babies born to 14–16 year olds, adjusted (n) mean, g** (28) 3423 / (17) 3028 / 395 ± 343 **MBW of babies of all smokers (≥ 5 cigarettes /day), adjusted (n) mean, g** (78) 3331 / (64) 3235 / 96 ± 177 **MBW of babies born to older non-smokers, adjusted (n) mean, g** (71) 3210 / (72) 3370 / –160 ± 172 **LBW (< 2500g) babies born to mothers of all ages, adjusted (n) %** (166) 5.78 / (142) 2.61 / 3.17 ± 4.01 **LBW rates babies born to 14-16 year olds, unadjusted (n) %** (28) 0.00 / (17) 11.76 / –11.76 **LBW rates babies born to all smokers, adjusted (n) %** (78) 1.46 / (64) 3.79 / –2.33 ± 4.12 **LBW rates babies born to older non-smokers, adjusted (n) %** (71) 10.57 / (72) 0.00 / 10.57 ± 5.20 / ≤ 0.01	Lost or dropped out from control groups (1 and 2) 12 Lost or dropped out of intervention groups (3 and 4) 14 **Reasons** Moved or miscarried Women in intervention groups who dropped out were found to have a significantly greater sense of control over their lives and higher education	Not enough detail of nutrition component of the intervention **Strength of evidence** ++

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 19 (cont.): Complex health and social care intervention RCT (Section 4.4: Complex health and social care interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
		Comparability of participants and women who declined to take part in the programme – No differences in age, marital status, education – Significant difference in proportion of non-white (94%) vs white women (80%) in the population enrolling ($p < 0.02$) Removed from analysis 20 cases with maternal or fetal conditions predisposing to pre-term delivery and/or aberrations in fetal growth were removed from the analysis to reduce the number of conditions subject to home-visiting (results of the analyses of these cases are similar to those reported in the main study)	(Only groups 3 and 4 got prenatal home visits – which was designed to enhance social support in the prenatal period, increase participation in other services like WIC, encourage healthy habits including a healthy diet, and obstetric status)	Groups 3&4 Nurse-visited / Groups 1&2 Controls / Diff & 95% CI / p Pre-term delivery mothers of all ages (n) % (166) 6.90 / (142) 7.27 / –0.37 ± 2.30 Pre-term delivery 14–16 year olds, unadjusted (n) % (28) 0.00 / (17) 11.76 / –11.76 Pre-term delivery all smokers (n) % (78) 2.08 / (64) 9.81 / 7.73 ± 7.05 / ≤ 0.05 Pre-term delivery older non-smokers (n) % (71) 11.83 / (72) 3.13 / 8.70 ± 7.68 / ≤ 0.05 Length of gestation all women, adjusted (n) mean, weeks (166) 39.57 / (142) 39.71 / –0.14 ± 0.45 Length of gestation 14–16 year old mothers (n) mean, weeks (28) 40.41 / (17) 39.71 / 0.70 ± 1.49 Length of gestation all smokers, adjusted (n) mean, weeks (78) 40.10 / (64) 39.46 / 0.64 ± 0.76 Length of gestation older non-smokers, adjusted (n) mean, weeks (71) 38.86 / (72) 40.03 / –1.17 ± 0.75 / ≤ 0.05 No. of services known at 32 weeks (n) mean (157) 5.47 / (137) 4.91 / –0.56 ± 0.45 / ≤ 0.01 Women attending childbirth education classes at 32 weeks (n) mean (129) 0.70 / (120) 0.54 / –16 ± 0.13 / ≤ 0.01 No. of nutrition supplement vouchers used at time of 2nd interview, (n) mean (152) 2.18 / (136) 1.56 / –0.62 ± 0.55 / ≤ 0.05 No. of antepartum visits at 32 weeks (n) mean (156) 10.49 / (136) 10.50 / 0.01 ± 0.67 Maternal weight gain (weight at last visit – pre-pregnant weight) (n) mean, kg (153) 16.2 / (136) 14.9 / –1.33 ± 1.42 Adequacy of diet at 32 weeks (n) mean (138) 73.86 / (115) 71.75 / 4.47 ± 4.38 / ≤ 0.05		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

Table 19 (cont.): Complex health and social care intervention RCT (Section 4.4: Complex health and social care interventions)

Author, year, country Research question Study design details	Participant selection Inc/exc criteria	Baseline characteristics of participants	Intervention details	Results	Losses	Additional comments, strength of evidence
				Groups 3&4 Nurse-visited / Groups 1&2 Controls / Diff & 95% CI / p Difference in number of cigarettes smoked/day (entry – 2nd visit) (n) mean (77) –2.54 / (64) 1.63 / 4.17 ± 1.01 / ≤ 0.001 Vaginal bleeding between 1st and 3rd trimester (n) mean (158) 0.00 / (137) 0.05 / 0.05 ± 0.07 Diastolic blood pressure between 1st and last visit (n) mean mm Hg (158) 7.60 / (137) 7.13 / –0.47 ± 2.96 Proteinurea (≤ 2+) after enrolment (n) mean, % (166) 0.05 / (142) 0.03 / –0.02 ± 0.04 Kidney infections after enrolment (n) mean, % (165) 0.00 / (141) 0.03 / 0.03 ± 0.02 / ≤ 0.01 **Costs:** Not reported **Views:** Not reported		

CT= controlled trial; RCT = randomised controlled trial; C = control; I = intervention; s/ns = significant/not significant; n = number; SD = standard deviation; LBW = low birth weight
Strength of evidence key: ++ all or most of the quality criteria fulfilled, + some of the criteria fulfilled, – few or no criteria fulfilled

APPENDIX 4

Quality appraisal tables

The following three tables show quality appraisal for the RCTs, controlled trials and before-after studies.

Key to tables:

RCT = randomised controlled trial
C = control
I = intervention

Table 1 – Randomised controlled trials

Study (name, year)	Clear inclusion and exclusion criteria ✓ = clear ✗ = not clear or not reported	Overall sample size [arms]	A priori sample size calculation ✓ = yes ✗ = no n/r = not reported/unclear	True randomisation ✓ = appropriate ✗= not appropriate n/r = not reported/unclear	Comparability of groups reported at baseline ✓ = comparable ✗ = not comparable n/r = not reported	Blinded outcome assessment ✓ = blinded ✗ = not blinded n/r = not reported/ unclear	Withdrawals ✓a = reported by group with reason ✓b = reported not by group or reason n/a = not reported or unclear n/a = no withdrawals	Intention-to-treat analysis ✓ = yes ✗ = no n/r = not reported/ unclear n/a = not applicable	Was methodology of dietary intake assessment appropriate? ✓ = yes ✗ = no n/r = not reported/unclear	Strength of evidence
Graham et al. 1992	✓	145 [I = 87, C = 58]	✓	✓	✗	n/r	✓a	✗	n/r	+
Hunt et al. 1976	✓	344 [I = 173, C = 171]	n/r	n/r	✓	n/r	✓b	✗	✓	+
Kafatos et al. 1989	✓	Clinics randomised [10 + 10] Women recruited 568 [I = 300, C = 268]	✗	n/r	✗	✗	n/r	✗	✓	–
Metcoff et al. 1985	✓inclusion ✗exclusion	410 [I = 238, C = 172]	n/r	✓	✗ (I group heavier at baseline	n/r	✓b	✗	✓	+
Olds et al. 1986	✓	400 [data provided for I = 189, C = 165]	✗	✓	✓	✓	✓a	✗	✓	++
Rush et al. 1980	✓	814 [I1 = 263, I2 = 272, C = 279]	✓	n/r	✓	✓	✓a	✓	✓	++
Sweeney et al. 1985	✓	43 [I = 22, C = 21]	n/r	n/r	✓	n/r	✓b	✗	✗	–

Table 2: Quality appraisal – Non-randomised controlled trials

Study (name, year)	Clear inclusion and exclusion criteria ✓ = clear ✗ = not clear n/r = not reported/	Overall sample size [arms]	A priori sample size calculation ✓ = yes ✗ = no n/r = not reported/unclear	Method of group allocation ✓ = appropriate ✗= not appropriate n/r = not reported/ u/c = unclear	Comparability of groups reported at baseline ✓ = comparable ✗ = not comparable n/r = not reported	Blinded outcome assessment ✓ = blinded ✗ = not blinded n/r = not reported/ unclear	Withdrawals ✓a = reported by group with reason ✓b = reported not by group or reason n/a = not reported or unclear n/a = no withdrawals	Intention-to-treat analysis ✓ = yes ✗ = no n/r = not reported/ unclear	Was methodology of dietary intake assessment appropriate? ✓ = yes ✗ = no n/r = not reported/unclear	Strength of evidence
Bailey 1983	✓inclusion ✗exclusion	89 [I = 43, C = 46]	n/r	✓	✓	n/r	n/r	✗	✓	–
Briley et al. 2002	✓inclusion ✗exclusion	27 [I = 15, C = 12]	✗	n/r	✗	n/r	✓a	✗	✓	–
Collins et al. 1985	✓	519 [I = 341, C = 178]	n/r	✓	✗	n/r	n/r	n/r	n/r	–
Doyle et al. 1992	✓	1082 [I = 756, C = 326]	n/r	✓	✗	n/r	✓a	✗	✓	+
Long et al. 2002	✓	301 [I = 136, three C groups = 65/group]	n/r	✗	n/r	n/r	n/r	✓	✓	–
Pehrsson et al. 2001	✓	110 [I = 57, C = 53]	n/r	✓	✓	n/r	✓b	✗	✓	+
Rush et al. 1988	✓	6563 [I = 5205, C = 1358]	✓	✓	✗	✗	✓a	✓	✓	+
Viegas et al. 1982a	✓inclusion ✗exclusion	153 [I1 = 51, I2 = 57 C = 451]	✗	u/c	✓	n/r	✓a	✗	✓	–
Viegas et al. 1982b	✓inclusion ✗exclusion	130 [I1 = 44, I2 = 45 C = 41]	✗	u/c	✗	n/r	✓a	✗	✓	–
Widga and Lewis 1999	✓inclusion ✗exclusion	81 [I = 55, C = 26]	n/r	✓	n/r	n/r	✓a	✗	✓	–

Table 3: Quality appraisal – Before-after studies

Study	Are the groups selected from a suitable sampling frame? ✓ = yes ✗ = no	Are both groups selected from the same sampling frame? ✓ = yes ✗ = no	Random sampling for both groups? ✓ = yes ✗ = no n/r = not reported	If not random, what method of sampling was used? (state method)	A priori sample size calculation ✓ = yes ✗ = no n/r = not reported	Clear inclusion and exclusion criteria ✓ = yes ✗ = no n/r = not reported	What factors (other than the intervention) may affect the outcome? (state factors)	Were groups comparable for possible confounding factors? ✓ = yes ✗ = no n/r = not reported	Did the authors adjust for the effects of confounders? ✓ = yes ✗ = no n/r = not reported	Withdrawals ✓a: reported by group with reason ✓b: reported not by group ✓c: reported not by reason n/r = not reported or unclear	Was the analysis appropriate? ✓ = yes ✗ = no	Was methodology of dietary intake assessment appropriate? ✓ = yes ✗ = no n/r = not reported/unclear	Strength of evidence
Edozien et al. 1979	✓	✓	✗	Not stated	✗	n/r	Participation in other welfare programmes	n/r	✗	n/r	✓	✓	–
Gray-Donald et al. 2000	✓	✓	n/r	n/r (convenience sample)	✗	✓	Other programmes; changes in prenatal care; women's views	✓	✗	✓b	✓	✓	+

APPENDIX 5

Economic evaluations

WIC studies

Schramm (1985) WIC prenatal participation and its relationship to newborn Medicaid costs in Missouri: a cost/benefit analysis

This study relates to Medicaid births in 1980 in Missouri where eligibility was < 195% of the federal poverty level. Costs were included for mother and newborn up to 30 days of age.

The study was based on linkage of Medicaid, birth certificates, WIC records, and NICU admissions. From 9062 Medicaid admissions, the database was eventually reduced to 1883 WIC and 5745 non-WIC women; attrition was due to matching problems, etc.

- The cost of increased WIC participation was estimated as the value of vouchers redeemed + 20% admin costs. This was offset against the reduction in Medicaid costs.
- LBW in WIC babies 10.7% vs 12.7% in non-WIC babies.
- Costs for mothers and babies were estimated separately. No difference was apparent in mothers' costs. WIC babies costs were lower at $574 vs $672 for non-WIC, adjusted for urban/rural differences.

Comment: Only limited testing of comparability of deleted records and WIC/non-WIC women. Problems with matching. Some inconsistent results. No sensitivity analyses.

Schramm (1986) Prenatal participation in WIC related to Medicaid costs for Missouri newborns: 1982 update

Update of 1985 study above. WIC eligibility changed to 175% of federal poverty level and population covered increased. Reimbursement to hospitals changed from 100% of charges for newborns to per diem formula based on whole admitted population and DRGs.

Study limited to newborns up to 45 days and based on linkage of Medicaid, birth certificates, WIC records, NICU admissions and death certificates. 10,196 Medicaid records cut down to 3261 WIC and 5285 non-WIC women after exclusions and deletions. Differences between excluded women and remainder 'not very substantial'.

- WIC costs defined as actual cost of redeemed food vouchers + 20% admin = $508,000.
- Mean birth weight and proportion LBW both reduced significantly in WIC women.
- LBW 10.1% in WIC, 13.1% non-WIC.
- NICU admissions 3.9% WIC vs 4.5% non-WIC.
- WIC women with greatest value of redeemed vouchers ($220+) had best outcomes and lowest costs of care.
- Medicaid paid claims: $1250 WIC, $1326 non-WIC.
- Cost-benefit ratio 1:0.49 (95% CI 1:0.07–0.90)

Comment: Problems with incomplete Medicaid cost data. Comparability of deleted cases and WIC/non-WIC not evaluated. No sensitivity analyses.

Joyce et al. (1988) A cost-effectiveness analysis of strategies to reduce infant mortality

Cost effectiveness of various strategies including WIC and prenatal care to reduce neonatal mortality (birth to 28 days) and LBW. Statistical modelling study using ordinary least squares (OLS) regression and two stage least squares (TSLS) regression. Inputs to equations included county level data on smoking, prenatal care, proportion 'high risk', etc.

- Cost = expenses of increasing utilisation by 1000 women but excluded the costs associated with attracting more women.
- Prenatal care costs included physician fee, transport, time costs. WIC cost included redeemed food vouchers + 20% admin cost.

Comment: Many of the inputs to equations were very crude, eg 'high risk' = aged 15–19 and 40–44. Costs are not reported in disaggregated form and source not stated. Assumption that additional users will be the same as current users. No sensitivity analyses.

Devaney, Devaney et al. (1990, 1992, 1998). The savings in Medicaid costs for newborns and their mothers from prenatal participation in the WIC program (plus another paper and book chapter from same study)

Restricted to Medicaid population in Florida, Minnesota, North and South Carolina in 1987, and Texas Jan–Jun 1988. Medicaid perspective; included women and newborn treatment costs; timeframe birth to 60 days. Where an episode spanned the 60 day limit, only the proportion occurring within 60 days was counted. Five states selected on the basis of their ability to provide data extracts, plus data on perinatal, ethnicity and geographic factors. Database constructed from linkage of Medicaid claims and eligibility files, WIC programme files, and vital records. Linkage ranged from 86–93%. Deleted cases did not differ significantly from remainder. Similarly, differences between WIC and non-WIC women were small except for prenatal care. Definition of prenatal WIC participation varied by state (certification, issue, redemption of food 'instrument').

- WIC programme cost = cost of food + admin and educational expenses calculated as a ratio of food costs. Treatment costs = Medicaid reimbursement.
- Reduction in LBW ranged from 2.2% to 5.1%. Adequacy of prenatal care, as measured by number of visits, had an independent effect on LBW. Despite differences in populations and programs in the five states, all were cost saving so authors consider that this is likely to be the case nationally. Stability over time was uncertain due to changes in eligibility.

Comment: No stats on comparability of deleted cases or comparability of WIC and non-WIC. No sensitivity analyses.

Buescher et al. (1993) Prenatal WIC participation can reduce low birth weight and newborn medical costs: a cost-benefit analysis of WIC participation in North Carolina

Medicaid population in North Carolina, 1988. Record linkage study including WIC, Medicaid, birth certificates, hospital claims data. Included hospital claims for services beginning within 60 days of birth.

- WIC programme costs = cost of vouchers redeemed + 20% admin cost.
- Logistic regression used to examine influence of sociodemographic and other factors on newborn care costs.
- Significant reduction in LBW and VLBW in white and non-white populations receiving WIC. Consequently care costs lower. Inverse correlation between length of WIC participation and care costs.

Comment: Nothing reported about quality of matching. Claims for services beginning within 60 days leads to over-estimate of cost differences because sicker babies may have extensive care beyond 60 days. No sensitivity analyses.

Avruch and Cackley (1995) Savings achieved by giving WIC benefits to women prenatally

Cost study from Medicaid perspective up to 1 year of age. Effectiveness of WIC based on weighted mean of 13 studies (mixture of Medicaid and non-Medicaid) on LBW and VLBW. Effect size ranged from 1.04–2.24 for LBW and 1.50–3.70 for VLBW.

Costs (including deaths) were estimated from Maryland hospital charge data for 1989 adjusted to reflect national costs, deflated to reflect actual costs and inflated to 1992 prices. Outpatient costs estimated from payment ratio for children aged < 1 year from Medicaid. Rehospitalisation costs were from a single study that had examined this by birth weight.

- Cost-benefit ratio 1:1.36-3.89 depending which data included.

Comment: Costing beyond first year would show greater savings. However, some of the costing was rather crude, eg outpatient costs as a ratio. Study dependent on quality of evaluations and how selected. There was no sensitivity analysis.

EFNEP studies

Burney and Haughton (2002) EFNEP: a nutrition education program that demonstrates cost-benefit

Expanded Food and Nutrition Education Program, 16 counties of Tennessee in 1997-98. Research questions around use of resources, nutrient intake and cost of programme. Societal perspective stated but not done, limited to programme and family.

Study population included women on low incomes defined as receiving benefits and/or incomes below federal poverty level. 384 women (90% power to detect 20% difference in behaviour) were randomly selected from a recruited sample of 470 with consecutive allocation to three groups: 'A' received intervention and collected food receipts; 'B' received intervention and were asked to recall food expenditure; 'C' delayed intervention.

Cost data from university finance system, overheads estimated at 33% consistent with federal grants. Benefits were assumed to last 3 or 5 years (from literature) and discounted at 3, 5 and 7%. Sensitivity analysis restricted to duration of benefit and discount rate.

- No significant difference in savings on food expenditure except when using a shopping list.
- Combined intervention groups ate more fruit and veg after the intervention.
- Group A not necessarily more accurate due to loss of receipts.

Comment: Consecutive allocation may cause bias. Food recall (group B) may be biased. Dubious assumption that educational intervention just as effective 3–5 years hence. Confusion between participation in WIC and adequacy of prenatal care. Only limited sensitivity analyses.

Rajgopal et al. (2002) Cost-benefit analysis indicates the positive economic benefits of the Expanded Food and Nutrition Education Program related to chronic disease prevention

Data for Virginia 1996. Perspective of programme sponsors. Intervention = 'Individualised' lessons (mean 10.4) to individuals or small groups in participants' homes.

Costs = resources to implement programme, included salaries, office space, utilities, equipment, supplies and travel expenses + 17% 'marginal excess burden' = $1,713,081.

'Benefits' = healthcare savings attributable to EFNEP by preventing/delaying various diseases or conditions including LBW. Effectiveness of EFNEP in achieving 'optimal nutrition behaviour' (ONB) estimated by before/after 24 hr food recall checklist. Cost of treating diseases and conditions from literature estimated at $17,880,626. Increased years of employment associated with absence or delay in disease associated with ONB from literature estimated at $343,354. Costs of lost productivity averted discounted at 5%.

- Cost-benefit ratio 1:10.64.
- Univariate sensitivity analyses estimated effect of changing disease incidence rates, proportion of disease caused by diet and number of graduates achieving ONB. Range of CBR resulting from sensitivity analyses 1:2.66–17.04.

Comment: 24 hour food recall may be biased. Heroic assumption that EFNEP graduates practice ONB for life. Averted costs of lost productivity assume that women are employed. More extensive multiway sensitivity analysis would have been appropriate. Costs of LBW could have been modelled beyond 1 year.

Schuster et al. (2003) Investing in Oregon's Expanded Food and Nutrition Education Program (EFNEP): documenting costs and benefits

Oregon EFNEP based on Rajgopal et al.'s Virginia model above. Data for 1999–2000.

- Intervention as above. Costs as described above, total direct cost $446,003.
- 'Benefits' as described above. Total averted costs $1,619,321.
- Cost-benefit ratio 1:3.63.
- Sensitivity analysis – retention of ONB reduced by 50% and 75% CBR 1:1.82 and 1:0.91 respectively. Reduction in osteoporosis due to diet is unknown, base case assumed 100%. Sensitivity analysis 50% CBR 1:1.94.

Comment: 24 hour food recall may be biased. Base case assumption that EFNEP graduates practice ONB for life.

Averted costs of lost productivity assume that women are employed. More extensive sensitivity analysis would have been appropriate. Costs of LBW could have been modelled beyond 1 year.

Breastfeeding studies

Tuttle and Dewey (1996) Potential cost savings for Medi-Cal, AFDC, food stamps and WIC programs associated with increasing breast-feeding among low-income among women in California

Modelling study based on low income among women in California in 1993. Estimated reduction in costs to Medi-Cal, AFDC, food stamps and WIC programme if all women breastfed exclusively for 6 months (excluding costs of maternity services). Timeframe 90 months.

Effects of increasing breastfeeding on fertility from earlier study; effects on gastro-intestinal (GI) disease and otitis media (OM) from literature.

Healthcare costs taken from 1993 reimbursement rates. WIC costs based on 1993 voucher packets. Costs of AFDC and food stamps at 1993 payment rates. Discount rates of 0, 2 and 4% for costs beyond 1 year.

- Exclusive breastfeeding for 6 months delayed pregnancy by an average of 3 months over base case. For the model, GI disease was reduced by 50% and OM by 15%.
- Breastfeeding associated with savings for all four programmes of $3442–4944 over 90 month period at 4% discount rate ($459–659 per year).

Comment: No sensitivity analysis.

APPENDIX 6

Excluded studies

Study	Reason for exclusion
Ahluwalia et al. 1992	Retrospective analysis of birth & WIC records
Brown et al. 1996	Review of WIC records and linked vital statistics
Copeland et al. 1987	Time-series analysis of data over 30 years
Caan 1987	Observational study of outcomes in current pregnancy compared with earlier pregnancies in same woman (retrospective selection)
Dubois et al. 1997	Retrospective chart review and analysis
Joyce 1999	Analysis of Medicaid and linked birth records
Kendal et al. 2002	Retrospective comparison to study
Kennedy et al. 1982	Retrospective review of prenatal and nutrition records
Kennedy and Kotelchuck 1984	Retrospective selection of sample and data
Kotelchuck et al. 1984	Retrospective analysis of birth and death records
Kowaleski-Jones 2002	Compared outcomes in sibling pairs discordant for mother's WIC participation; data collected retrospectively from National Longitudinal Survey of Youth
Millard et al. 1999	Chart review to study multi-disciplinary support programme
Muscati et al. 1996	Retrospective cohort study of nutritional counselling
Nason 2002	Comprehensive care co-ordination studied; historical records used for control group
Odent et al. 1985	Parity matched observational comparison study of effects of nutritional advice
Orstead et al. 1985	Retrospective study of nutrition counselling using birth record data
Rush et al. 1988	'Historical' study using WIC records and data off vital statistics records
Stockbauer 1986	Retrospective analysis using data from birth and death certificates
Stockbauer 1987	Retrospective study using data from birth and death certificates
Zotti 1995	Retrospective comparative cross-sectional study using WIC records, birth certificates and nursing records

References

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Dubois S, Coulombe C, Pencharz P et al. (1997) Ability of the Higgins Nutrition Intervention Program to improve adolescent pregnancy outcome. *Journal of the American Dietetic Association* 97 (8):871–8.

Kendal AP, Peterson A, Manning C et al. (2002) Improving the health of infants on Medicaid by collocating special supplemental nutrition clinics with managed care provider sites. *American Journal of Public Health* 92 (3):399–403.

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APPENDIX 7 Evidence of effectiveness

	[1]	[2]	[3]	[4]	[5]	[6]	[7HP]	[7BEP]	[8]	[9]	[10]	[11C]	[11S]	[12]	[13]	[14]	[15]	[16]	[17]	[18]	[19]
Strength of evidence	–	–	–	+	+	+	++	++	–	–	–	+	+	+	+	–	–	–	–	+	++
LBW																					
MBW of babies born to all intervention group women																					
MBW of babies born to smokers																					
MBW of babies born < 37 weeks																					
MBW > 4kg																					
IUGR/SBA babies																					
Pre-term birth < 37 weeks																					
Early pre-term birth																					
Gestational age/duration of gestation																					
Baby head circumference																					
Neonatal mortality																					
Infant weight																					
Infant head circumference																					
Behavioural/psychological outcomes in children																					
Maternal weight change																					
Haemoglobin concentration																					
RBC folacin																					
Serum folacin																					
Transferrin saturation																					
Hematocrit																					
Low hematocrit																					
Serum iron																					
Rate of anaemia																					
Pregnancy complications																					
Breastfeeding initiation/at 6 weeks																					
Nutrition counselling sessions																					
Prenatal visits																					
Smoking																					
Programme quality x LBW																					
Programme quality x head circumference																					
Dietary intake energy																					
Dietary intake protein																					
Dietary intake folic acid																					
Dietary intake of B6																					
Dietary intake of iron																					
Dietary intake of thiamin																					
Dietary intake of riboflavin																					
Dietary intake of vitamin C																					
Dietary intake of calcium																					
Nutrition knowledge																					
Rate of caesarean section																					

KEY TO STUDIES:		
[1]	Bailey 1983	WIC
[2]	Collins et al. 1985	WIC
[3]	Edozien et al. 1979	WIC
[4]	Metcoff et al. 1985	WIC
[5]	Pehrsson et al. 2001	WIC
[6]	Rush et al. 1988	WIC
[7HP]	Rush et al. 1980	Stand-alone supplement high protein
[7BEP]	Rush et al. 1980	Stand-alone supplement balanced energy protein
[8]	Viegas et al. 1982a	Stand-alone supplement Asian women
[9]	Viegas et al. 1982b	Stand-alone supplement high-risk Asian women
[10]	Briley et al. 2002	Nutrition advice
[11C]	Doyle et al. 1992	Nutrition counselling
[11S]	Doyle et al. 1992	Nutritional supplement
[12]	Gray-Donald et al. 2000	Nutrition education
[13]	Hunt et al. 1976	Nutrition education
[14]	Kafatos et al. 1989	Nutrition education
[15]	Long et al. 2002	Nutrition education
[16]	Sweeney et al. 1985	Nutritional advice
[17]	Widga and Lewis 1989	Nutrition advice
[18]	Graham et al. 1992	Complex health and social care intervention
[19]	Olds et al. 1986	Complex health and social care intervention

KEY TO EFFECTIVENESS:	
	Not significant + evidence weak
	Not significant + moderately strong evidence
	Not significant + strong evidence
	Significant in favour of intervention group + evidence weak
	Significant in favour of intervention group + moderately strong evidence
	Significant in favour of intervention group + strong evidence
	Significant causing harm + not statistically significant + strong evidence
	No evidence

KEY TO STRENGTH OF EVIDENCE:	
–	Weak
+	Moderately strong
++	Strong

APPENDIX 8

Cochrane reviews of macro- and micro-nutrient intakes related to pregnancy

Nutrient [reference]	Intervention	Outcomes	Settings	Favourable effects	No effect	Unwanted effects	Unresolved issues
Calcium [1]	Supplementation during pregnancy	Hypertensive disorders of pregnancy	Developed and developing countries	Reduces the risk of high blood pressure in pregnancy especially in communities with low dietary calcium intake	Premature birth Stillbirth	None	Optimum dose of supplement
Energy and protein [2]	Advice to increase or reduce intake Supplementation/ restriction of calories/protein during pregnancy	Intake of energy/ protein Gestational weight gain Pregnancy outcome	Developed and developing countries	Energy-protein supplementation with no more than 25% protein produces modest increases in fetal growth and improves fetal and neonatal survival	Advice to increase energy/protein is unlikely to effect fetal, neonatal and infant health	High protein diets restrict fetal growth Restriction of energy in overweight pregnant women adversely affects fetal growth	
Folate [3]	Periconceptional supplementation	Prevalence of neural tube defects	Developed countries	Strong protective effect against neural tube defects			Fortification of basic food stuffs
Folate [4]	Supplementation in pregnancy	Haematological and biochemical parameters Pregnancy outcomes	Developed and developing countries	Improvement in haemoglobin levels and folate status			Clinical outcomes for mother and baby
Iron [5]	Supplementation in pregnancy	Haematological and biochemical parameters Pregnancy outcomes	Developed and developing countries	Prevention of low haemoglobin at the time of delivery and 6 weeks postpartum			Maternal and fetal outcomes
Iron and folate [6]	Supplementation in pregnancy	Haematological and biochemical parameters Pregnancy outcomes	Developed and developing countries	Prevention of low haemoglobin at the time of delivery			
Magnesium [7]	Supplementation in pregnancy	Maternal, neonatal and paediatric outcomes	Developed and developing countries				Maternal and fetal outcomes Maternal, neonatal and paediatric outcomes

APPENDIX 8: Cochrane reviews of macro- and micro-nutrient intakes related to pregnancy (cont.)

Nutrient	Intervention	Outcomes	Settings	Favourable effects	No effect	Unwanted effects	Unresolved issues
Vitamin A [8]	Supplementation in pregnancy	Clinical and biochemical outcomes for mother and baby	Developed and developing countries	Reduction in night blindness in women		Miscarriage, birth defects with high dosage	
Vitamin B 6 (pyridoxine) [9]	Supplementation in pregnancy and labour	Not clear	Developing countries	Reduction in dental decay in pregnant women			
Vitamin D [10]	Supplementation in pregnancy	Pregnancy outcome	Developed countries				Pregnancy outcome
Salt [11]	Advice to reduce salt intake during pregnancy	To reduce the risk of pre-eclampsia	Developed countries only				Advice to reduce salt intake on pre-eclampsia
Zinc [12]	Supplementation in pregnancy	Maternal and fetal mortality and morbidity	Developed countries				Maternal and fetal mortality and morbidity Pre-term birth
Nutrients [13]	Carnitine (amino acid releasing energy from fat), solcoseryl (protein-free calf blood), glucose, galactose for pregnant women	Fetal growth impairment Perinatal outcomes	Developed countries				Fetal growth impairment Perinatal outcomes

1 Attalah AH, Hofmeyr GJ, Duley L (2002) Calcium supplementation in pregnancy for preventing hypertensive disorders and related problems. *The Cochrane Database of Systematic Reviews* 2002, Issue 1.

2 Kramer M, Kakuma R (2003) Energy and protein intake during pregnancy. *The Cochrane Database of Systematic Reviews* 2003, Issue 4.

3 Lumley J, Watson L, Watson M et al. (2001) Periconceptional supplementation with folate and/or multivitamins for preventing neural tube defects. *The Cochrane Database of Systematic Reviews* 2001, Issue 3.

4 Mahomed K (1997) Folate supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1997, Issue 3.

5 Mahomed K (1999) Iron supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1999, Issue 4.

6 Mahomed K (1997) Iron and folate supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1997, Issue 4.

7 Makrides M, Crowther CA (2001) Magnesium supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 2001, Issue 4.

8 van den Broek N, Kulier R, Gulmezoglu AM et al. (2002) Vitamin A supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 2002, Issue 4.

9 Mahomed K, Gulmezoglu AM (1997) Pyridoxine supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1997, Issue 1.

10 Mahomed K, Gulmezoglu AM (1999) Vitamin D supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1999, Issue 1.

11 Duley L, Henderson-Smart D (2000) Reduced salt intake compared to normal dietary salt, or high intake, in pregnancy. *The Cochrane Database of Systematic Reviews* 2000, Issue 2.

12 Mahomed K (1997) Zinc supplementation during pregnancy. *The Cochrane Database of Systematic Reviews* 1997, Issue 3.

13 Say L, Gülmezoglu AM, Hofmeyr GJ (2003) Maternal nutrient supplementation for suspected impaired fetal growth. *The Cochrane Database of Systematic Reviews* 2003, Issue 1.

APPENDIX 9

Glossary – terms used in this review and in the literature

AFDC	Aid to Families with Dependent Children
ALSPAC	Avon Longitudinal Study of Pregnancy and Childhood
BMI	Body mass index
CBR	Cost-benefit ratio
CES	Cooperative Extension Service
COMA	Committee on Medical Aspects of food and nutrition policy
CRD	Centre for Reviews and Dissemination, York
CT	Non-randomised controlled trial
DAI	Dissertation Abstracts International
EFNEP	Expanded Food and Nutrition Education Programme
FFQ	Food frequency questionnaire
IUGR	Intrauterine growth retardation
LBW	Low birth weight
MBW	Mean birth weight
MLBW	Moderately low birth weight
MUAC	Mid-upper arm circumference
NDM	National Dried Milk
Perinatal outcomes	Low birth weight, mean birth weight, length at birth, gestational age, pre-term birth, intrauterine growth retardation, fetal survival, perinatal mortality
Perinatal period	From 22 completed weeks of gestation to 7 completed days after birth
PIH	Pregnancy induced hypertension
Pregnancy outcomes	Maternal morbidity, maternal mortality
RCT	Randomised controlled trial
RDA	Recommended daily allowance RDA is a recommendation for nutrient intake for a population group. It is the quantity that should be consumed to derive what is needed. RDA depends on age and physiological condition (eg pregnancy)
RNI	Reference nutrient intake RNI is the estimated amount of a nutrient that will be enough for almost everyone in the population. This level of intake is, therefore, higher than most healthy people need and if individuals are consuming the RNI they are most unlikely to be deficient in that nutrient. It is prudent for those planning diets for groups of people that most nutrients are provided at the RNI to ensure that the nutritional requirements of most people are met.
SCBU	Special care baby unit
SWS	Southampton Women's Survey
USDA	United States Department of Agriculture
VLBW	Very low birth weight
WIC	Speical Supplemental Programme for Women, Infants and Children