Pregnancy Evidence Tables

Evidence is presented to answer the following questions:

Folate/Folic Acid

1. What interventions are effective in increasing awareness and knowledge among pregnant women of the recommended daily intake of folate and folic acid?

2. What interventions other than folic acid fortification of food are effective in increasing dietary folate intake of pregnant women?

3. What interventions are effective in increasing the uptake of folic acid supplements in pregnant women?

4. What interventions are effective in increasing health professionals knowledge and awareness about recommendations for folate and folic acid in pregnant women?

Omega 3 supplements/fish oils

5. a) What interventions are effective in increasing awareness and knowledge among pregnant women about the benefits of eating recommended amounts of oily fish and vegetarian sources of omega-3 supplements during pregnancy?

   b) What interventions are effective in altering oily fish consumption among pregnant women?

Alcohol

6. Excluding interventions that are aimed specifically at problem alcohol users what interventions are effective in reducing alcohol intake among the general population of pregnant women?

Food safety advice

7. a) What interventions are effective in increasing awareness and knowledge about food safety advice among pregnant women?

b) What interventions are effective in changing food safety practice among pregnant women?

Education and counselling to improve nutrition

8. a) What educational interventions that are aimed at all pregnant women are by themselves effective in improving dietary intake and nutritional status?

   b) What educational interventions that are targeted at a defined group of pregnant women, for example, low income or ethnic minorities are by themselves effective in improving their dietary intake and nutritional status?

Food support programmes, financial incentives and multiple interventions to improve nutrition

9. a) Do interventions that include the provision of food or vouchers or incentives to buy specific foods improve dietary intake and nutritional status of pregnant women?

   b) What interventions either by themselves or in addition to counselling and educational support are effective in improving the dietary intake and nutritional status of pregnant women?

1. What interventions are effective in increasing awareness and knowledge among pregnant women of the recommended daily intake of folate and folic acid?

Studies to be included	Evidence type included	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic review</u> none <u>Randomised trials</u> none <u>UK studies</u> none	No randomised trials were found that focussed only on women that are already pregnant. The crucial period for preventing neural tube defects is the early stages of pregnancy. Therefore awareness campaigns focus on the need to take folic acid around the peri-conceptual period. In the UK this is especially important as many pregnancies are unplanned. The Health Education Authority ran a mass media campaign in England to increase awareness of the need to take folic acid and this was successful in increasing awareness in all women of child bearing age.

2. What interventions other than folic acid fortification of food are effective in increasing dietary folate intake of pregnant women?

Studies to be included	Evidence type included	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review none Randomised trials none UK studies none	No randomised trials or UK studies were found that measured dietary folate in pregnant women before and after an intervention. Interventions that improve overall nutrition in pregnant women might also increase dietary folate intake. Performing a robust study that includes a control population in women that are pregnant is likely to be very difficult because of ethical considerations.

3. What interventions are effective in increasing the uptake of folic acid supplements in pregnant women?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review none Randomised trials Robins 2005 UK studies HEA folic acid campaign 1995-1998	The evidence to answer this question comes from a systematic review, a well conducted randomised trial from the USA and a large multi-intervention public health campaign in England.	The evidence comes from interventions aimed at women who are not yet pregnant. The large HEA public health campaign increased sales and prescriptions of supplements. It should be noted that this campaign was aimed at women and health professionals. The trial in the USA by Robins indicate that interventions involving counselling by a physician and free folic acid supplements increase usage of supplements in pre-pregnant women. It would be somewhat perverse if a similar intervention did not increase usage in women known to be in early stages of pregnancy.

Evidence Tables

First author and date	Study design, Setting Study type and quality	Study population	Research question Power calculation	Intervention Comparisons Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Quality, Funding
Robbins 2005 USA	RCT 1+	The study took place in Arkansas USA. It included women between the ages of 18 and 45 years attending 1 of 4 clinics for a routine gynecological visit in The study excluded women who were pregnant, visiting for care, unable to speak and understand English, or had a hysterectomy, tubal ligation, or a previous pregnancy affected by a neural tube defect (NTD) 322 women were randomised to two groups 162 intervention group and 160 to control. At baseline, groups did not differ in demographic characteristics, pregnancy	To determine the impact of a physician intervention during routine gynecologic visits on women's intake of folic supplements Anticipating a baseline daily folic acid intake of 32% and a 20% loss to follow-up, the researchers determined 158 in each group were needed for 80% power to detect a difference of ≥15% in increased daily folic acid intake between the groups at a probability value of ≤0.05%	**Intervention group** n=162 received short scripted counselling on the benefits of folic acid from the gynecologist, 30 folic acid tablets and written information about the benefits of folic acid. They also received a reminder phone call from a research nurse 1-2 weeks later **Control group** n=160 Received 30-60 second scripted physician counselling on general preventive behaviours (breast self-examination, seat belt use, or sunscreen use), a coupon for 30 free folic acid tablets with SAE, and the same written information about folic acid.	Daily folic acid use Group Before After Int n=139 23.7% 39.6% Control n=140 23.6% 36.4% (p= 0.549) At least weekly folic acid use Group Before After Int n=139 38.1% 64.0% Control n=140 42.9% 51.4% p=0.008 Among those in the intervention group 26% moved from no intake of folic acid to taking it at least weekly. In these women the average number of days per week of folic acid use was 5.1. Further subgroup analyses are reported suggesting the intervention was more effective among black women, women with household income <$30,000, women not planning pregnancy and women aware of the benefits	The brief counselling and written information and free supply of folic acid supplements appear applicable to the UK The intervention increased self reported use of folic acid. As the control population also received a leaflet and voucher for folic acid the study might underestimate the effect of free folic acid supplements accompanied by physician counselling.

First author and date	Study design, Setting Study type and quality	Study population	Research question Power calculation	Intervention Comparisons Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Quality, Funding
		intentions, folic acid awareness or preventive health behaviours		Follow up: The intervention was evaluated by follow-up telephone calls 2 months later using standard questions about intake of folic acid and vitamins. Follow-up rate 87%.	of folic acid than among the whole sample	A non-randomised but well run study by de Weerd (Preconception counseling improves folate status of women planning pregnancy. *Obstetrics & Gynecology* 2002;99:45-50.) found that a consultation about folic acid with free supplements improved red cell folate levels in blood samples.

Changing preconceptions. The Health Education Authority Folic Acid Campaign 1995-1998. HEA1998

First author and date	Study design, Setting Study type and quality	Study population	Research question Power calculation	Intervention Comparisons Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Quality, Funding
HEA 1998	Before and after monitoring of a whole population public health intervention 2+	The public education campaign initially focused on women planning pregnancy. In its second year, activity broadened to include all women of childbearing age with the aim of increasing awareness of the benefits of folic acid for possible pregnancies which could be some years away. Young people were the target of further public education in the third year of the campaign.	To increase awareness of the importance of taking additional folic acid before and until the 12th week of pregnancy The campaign also aimed to increase awareness among professionals, increase availability of fortified breads and cereals, increase availability of appropriate supplements, and increase £2.3 million national public education campaign	Advertising; A range of media and public relations activities; Creation and distribution of leaflets and posters; Provision of a freephone advice line. Volume of sales of 400mcg folic acid supplements were monitored using manufactures data. Volume sales in February 1996 were used as the baseline Prescription rates of 400mcg folic acid were monitored from the start of the campaign Campaign ran for three years from 1995-1998	Eight months after the start of the campaign sales of 400mcg folic acid supplements were 40% higher. Sixteen months after the start of the campaign sales of 400mcg folic acid supplements were 47% higher. Prescription rates of 400mcg folic acid in England were 55% higher in the third quarter of 1997 than at the start of the campaign	It is not known if the increase in sales and prescriptions of folic acid was mainly because of increased intake by pregnant women or increased intake by none pregnant women.

4. What interventions are effective in increasing health professionals knowledge and awareness about recommendations for folate and folic acid in pregnant women?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review none Randomised trials none Evaluations of UK Campaigns HEA folic acid campaign 1995-1998	The evidence to answer this question comes from a large multi-intervention public health campaign in England. The campaign targeted women and a range of health professionals. The impact of the campaign on health professionals was appropriately evaluated using quantitative questionnaires and some qualitative interviews.	The campaign used multiple methods to increase awareness and it is not possible to distinguish which interventions are most effective. The campaign was successful in raising awareness among health professionals about the need for folic acid supplements in women planning a pregnancy but only raised the proportion of health professionals that would spontaneously mention folic acid to pregnant women from 36% to 39%. There was also evidence that after the campaign many health professionals were unclear about the correct dosage and duration.

Evidence Table

First author and date	Study design Quality	Participants	Intervention Evaluation	Outcome/Results	Comments
HEA 1998	Before and after survey To assess impact of a public health interven tion 2+	The professionals surveyed were dieticians /nutritionists, family planning doctors, family planning nurses, GPs, health visitors, midwives, obstetricians/gynaecologi sts occupational health nurses, pharmacists, practice nurses and school nurses.	The campaign's aim for health professionals was two-fold: 1) to provide them with information and resources concerning folic acid and the Government recommendations; 2) to increase their skills and competencies to help them advise and inform their patients, clients or customers about folic acid by using HEA material. Through a combination of publicatiouns, advertising, media work and professional seminars, information was communicated to: dieticians family planning doctors and nurses GPs, health promotion specialists health visitors, midwives, nutritionists, obstetricians, pharmacists, practice nurses, public health professionals school-based professionals and others in contact with young	Doctors (GPs, family planning doctors, obstetricians and gynaecologists) had the most contact with both women planning pregnancy and pregnant women. When asked about advice to women planning a pregnancy 55% in 1996 and 71% in 1997 spontaneously mentioned folic acid. When asked about providing advice to pregnant women the table describes the proportion of health professionals spontaneously mentioning each type of advice 1996 1997 Alcohol 25% 61% Diet 63% 77% Smoking 36% 77% Exercise 13% 44% Folic acid 36% 39% When asked specifically about dietary supplements for women planning a pregnancy 73% in 1996 and 81% in 1997 reported folic acid.	These data offer an important snapshot into knowledge about folic acid among professionals working in England. The data suggest that after a widespread campaign to increase awareness most professionals were aware of the importance of folic acid. However many professionals did not know the correct dosage or most appropriate timing for folic acid supplements.

			people. Two quantitative surveys were undertaken. Approximately 600 professionals were interviewed in 1996 before the campaign. The health professionals were recruited in equal numbers rather than weighted in terms of numbers in the workforce. Therefore the sample is not representative of all the target professionals. A second survey of approximately 1100 professionals was undertaken in 1997 and provides follow-up.	In both surveys when specifically asked 73% of the professionals knew that folic acid was to be taken before conception and in the first twelve weeks. In 1996 when asked about dosage in women planning a pregnancy 41% answered correctly in 1997 the figure was 45%. Food sources seen by health professionals to be rich in folic acid 1996 1997 Green leafy veg. 66% 65% Vegetables 15% 29% Cereals 18% 28% Fruit 11% 19% Bread 6% 19%	

Omega 3 supplements/fish oils

5. a) What interventions are effective in increasing awareness and knowledge among pregnant women about the benefits of eating recommended amounts of oily fish and vegetarian sources of omega-3 supplements during pregnancy?

   b) What interventions are effective in altering oily fish consumption among pregnant women?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review none Randomised trials none UK Studies Odent 1996	Only one study was found which was related to this question. The study was unable to demonstrate that advice to eat fish resulted in improved pregnancy outcomes. The amount of fish consumed by the women in the intervention group was not recorded. A survey of 40 intervention group women offers some weak evidence that the intervention increased fish consumption.	The author of the one included study reports [BMJ. 2002 May 25; 324(7348): 1279] that their team repeated the study in three different populations and could not demonstrate a benefit in terms of birth weight and duration of pregnancy.

Evidence Table

First Author date	Study design quality	Participants	Intervention	Main results	Comment
Odent 1996	Case control observational study 2+	Cases were 499 women undergoing prenatal care in an East London Hospital between January 1991 and December 1992 Controls were the next woman on the birth register with the same parity as a case. All controls were women that did not receive the counselling but did attend for prenatal care.	The cases received a counselling session of approximately 20 minutes duration at a hospital antenatal clinic before 20 weeks gestation. The session covered women's current diet, their likes and dislikes and explained the benefits of eating oily fish. An objective was to raise consciousness about fetal growth and the needs of the developing brain. The women were advised to reduce intake of transfatty acids found in biscuits and cakes and increase their intake of oily fish. According to the women's tastes and needs they were offered a selection of printed recipes for oily fish dishes. The controls received no dietary intervention.	There were 19 losses to follow-up and 470 cases were compared with 464 controls. Parity was uncertain for two cases and controls and were omitted from analysis Cases n=468 Controls n=462 odds ratio confidence interval Birth <37 weeks 7.3% 9.5% 0.74 0.45-1.2 Weight <2500g 4.7% 6.7% 0.69 0.38-1.2 Cases Controls Mean Diff confidence interval Birthweight (g) 3349 3284 65 -4-133 Head circ (cm) 34.65 34.45 0.20 0.01-0.39 Gest age (weeks) 39.57 39.44 0.13 -0.11-0.38 Questionnaire given to 40 random cases. Of which 39 completed; 32 mentioned that they ate more fish; 19 mentioned that they had eliminated certain foods; 13 claimed the advice had influenced their breakfast habits and five claimed it had no influence on their eating habits.	The study used a simple intervention and was on the whole adequately undertaken. The only significant difference was for head circumference. However no power calculation is reported so it is unclear if the lack of effect found was due to the study being underpowered. Two other possibilities for a lack of effect are that the dietary counselling had little or no impact on fish eating or that increased fish consumption after the early stages of pregnancy has little impact on the outcomes measured. The questionnaire data offers some weak evidence that counselling has an impact on some women's dietary behaviour.

6. Excluding interventions that are aimed specifically at dependent alcohol users what interventions are effective in reducing alcohol intake among the general population of pregnant women?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic Reviews</u> Schorling 1993 <u>Randomised trials</u> Chang 1999 Chang 2005 Reynolds 1995 <u>UK Studies</u> Waterson 1990	The evidence to answer this question comes from studies undertaken in pregnant women. Most of the studies contain important methodological flaws. The only RCT which is graded 1+ found no difference between the intervention and control groups but in both groups drinking fell substantially making it difficult to interpret the results. All the studies used self reporting to measure alcohol intake which might lead to bias. The study by Waterson is included in the Schorling review but is presented as a separate evidence table.	A recent systematic review of the fetal effects of low-to-moderate alcohol consumption in pregnancy found that, for most outcomes, there was no consistent evidence of adverse effect across different studies. (Gray R. Review of the fetal effects of prenatal alcohol exposure. Report to DH 2006) Nevertheless drinking alcohol whilst pregnant is usually considered socially undesirable. This presents a problem for any large scale study because measuring actual alcohol intake among pregnant women is unfeasible but reported alcohol intake may be biased due to poor estimation, recall bias and under reporting of drinking. In all the studies included here reported alcohol consumption fell in both the intervention and control groups. This consistent finding could be due to a reporting bias or it might reflect an actual decrease in alcohol drinking as pregnancy progresses irrespective of any intervention or it might be that assessment alone is sufficient to reduce alcohol consumption.

Evidence Tables

First author date	Study Design quality	**Review Question**: To critically review published investigations of prenatal education and counselling for reducing alcohol consumption during pregnancy **Inclusion criteria Search strategy Studies included**	**Main results**	**Summary**	**Confounders/ Comments**
Schorling 1993	Systematic review 2+	<u>Inclusion criteria</u> Prospective determination of alcohol use among a cohort of pregnant women. Provision of a specific intervention to women at risk. Determination of alcohol use in individual women following the intervention. <u>Search strategy</u> Medline 1973 – 1991	Study / Population / control group / Results Meberg 1986 / all women / yes / 53% abstained* 41% reduced Waterson 1990 / all women / yes / 63-69% abstained* 18-22% reduced Larsson 1983 / all women / no / 70% abstained or reduced Rossett 1983 / heavy drinkers / no / 39% abstained 28% reduced Halmesmaki 1988 / heavy drinkers / no / 65% reduced * this reduction was not significantly different from the control group	Of the 5 studies included the author considered that only one was of acceptable quality Waterson and Murray-Lyon 1990 There were no RCT's and only 2 compared the treatment group to a control group Meberg et al 1986 and Waterson. The other three studies are case series. Both of the studies with control populations found no difference in alcohol use between control and intervention groups.	The review is of a good quality but the studies included were not high quality. However a consistent finding is that in all studies women reduced their intake of alcohol during prgnancy.

		ETOH Bibliographies of primary sources. Included Studies Meberg 1986 Waterson and Murray-Lyon 1990 Larsson 1983 Rosett et al 1983 Halmesmaki 1988		In all studies the majority of participants reduced their alcohol intake or abstained by the end of pregnancy.	

First author Year Country Study design Quality	Study population Inclusion/ exclusion criteria Total participants, number randomised to each group Participant characteristics	Research question Power calculation	Intervention Comparisons Length of follow-up, follow-up rate	Main results Only those reported by intervention group Effect size, CI	Applicability to UK Confounders/ Comments Funding
Chang 1999 USA RCT 1-	1165 Pregnant women initiating prenatal care in Boston USA. 886 agreed to be surveyed (survey included T-ACE alcohol screen) and 532 (60%) were TACE screen positive. 30% of the 532 women were excluded. Exclusion criteria Gestational age >28 weeks; No alcohol consumption in previous 6 months; Miscarriage in time between survey completion and telephone interview; Intention to receive prenatal care elsewhere; Non-English speaking;	To assess the impact of a brief intervention on antepartum alcohol consumption No power calculation is reported	Comprehensive health assessment carried out for both treatment groups which took 2 hours this included questions about alcohol <u>Intervention group only</u> Brief intervention – approx 45 minutes Women met with researcher at conclusion of the comprehensive health assessment Intervention included: Review of general health and course of pregnancy to date Review of lifestyle changes made since pregnancy including work, exercise, diet, smoking, and alcohol consumption	<u>Reduction in alcohol consumption between assessment and birth:</u> Control group averaged a net decrease of 0.4 drinks per drinking day and the Intervention group averaged a net decrease of 0.3 drinks per drinking day. The difference in reduction of antepartum drinks per drinking day was not statistically significant (p>0.05). The I and C groups did not differ on the number of drinking episodes in the antepartum period (0.7 v 1.0 episode, p = 0.12) Risk of antepartum alcohol consumption was increased threefold for participants who drank any alcohol while pregnant before the assessment or intervention (RR = 2.96, p= 0.0001), and surprisingly for those who intended to breastfeed(RR =	US study but no reason why it would not be applicable to UK settings Well educated and high socio-economic status sample There was no power calculation and no difference was found between the two groups. The control population reduced drinking more than the intervention group. There is probably a "hawthorn effect." As both the control and study populations had a comprehensive alcohol assessment, and drinking fell in both groups it appears likely that for both groups participation in the study and the overall focus on alcohol

	Intended abortion or false pregnancy; Current substance abuse treatment. Of the remainder the first 250 eligible women were included and randomised. <u>Participants</u> Total randomised 250 Intervention (brief intervention) n = 123 Control (assessment only) n = 127 No statistically significant demographic differences between treatment groups Mean age 30.7 ± 5.4 (range		Request that the participant articulate her drinking goals while pregnant and their reason Identification of alternatives to drinking when she is tempted to drink Summary of session by emphasising 4 key points – drinking goal, motivation, risk situations for drinking and alternatives to alcohol – and noting them in the take home manual. All intervention group were informed of the recommendation of prenatal abstinence being the most prudent drinking goal. Control group Comprehensive health and alcohol assessment only Follow-up post-partum interview for all women at same time as first postpartum obstetric visit Interview conducted by a second researcher Follow-up rate 247/250 (99%)	2.71, p = 0.003) Those who were abstinent pre-assessment (n = 143) and who received the intervention were more likely to maintain their abstinence (86% v. 72%, p = 0.04**).** Among the 72 abstinent pre-assessment participants with the earliest study enrolment, I group had half as many drinking episodes as C group (0.3 v. 0.6, p = 0.02). 107 (43%) women consumed an average of 1.8 (±1.4) drinks per drinking day pre assessment. Between assessment and birth this group averaged a decrease of 1.2 (±0.8) drinks per drinking day. 52 (49%) were abstinent after assessment and 21 (20%) reduced alcohol consumption, 12 (12%) increased and 20 (19%) made no change in the amount of alcohol consumed. There were no differences in drinks per drinking day or drinking episodes between treatment groups. Birth Outcome There were no statistically significant differences in the mean birth weights between C and I mothers (3406g v 3360g) or in mean 1 and 5 min. Apgar scores (C group 7.8 and 8.7, I group 8.1. and 8.9).	had a stronger effect than the intervention. Funding National Institute on Alcohol Abuse and Alcoholism

First author, Year, Country, Study design, Quality	Study population Inclusion/ exclusion criteria number randomised Participant characteristics	Research question Power calculation Funding	Intervention Comparisons Length of follow-up, follow-up rate	Main results Only those reported by intervention group Effect size, CI	Confounders/ Comments Applicability to UK Funding
Chang 2005 USA RCT 1_+	Potential participants attended an obstetrics practice in Boston the Inclusion criteria Positive T-ACE score Inclusion criteria Attending first prenatal visit at gestation <28 weeks; screened at risk for prenatal alcohol use (instrument, T-ACE, referenced in the paper); husband/ biological father of the child willing to participate Exclusion criteria Current treatment for alcohol abuse/ dependence); current use of / treatment for illicit drugs/ substances; intention to terminate the pregnancy 304 randomised [I= 152; C= 152] Participants were predominantly white (79%) and married (81%). Median age 31.4 years, median education level 4 year college degree or equivalent. Their	To test the effectiveness of a brief intervention in the reduction of prenatal alcohol consumption by women when a partner is included Sample size based on 95% confidence level, 90% power, 1:1 ratio of treatment and control groups, and expectation that 50% of control group would become abstinent. Allowing for 10% attrition rate, total number of participants needed was 295.	Intervention: given by trained clinicians. Included knowledge assessment/ feedback, contracting/ goal setting and behavioural modification in a single session of 20 – 25 minutes Control: no session Alcohol consumption was compared Follow-up was after the birth of the baby Overall follow-up rate 95% I 93% (142/152), C 96% (146/152)	No statistically significant differences between the groups in alcohol consumption pre-pregnancy. On average the groups consumed alcohol on 20% of days, mean 1.8 drinks per episode, with <10% abstinent. No statistically significant differences between the groups whilst pregnant but before study enrolment. On average the groups consumed alcohol on 5% of days, mean >1.5 drinks per episode, with <20% abstinent. Reported alcohol consumption after study enrolment declined in intervention and control groups. Mean days consumed alcohol 1.9% [I] and 2.0% [C] Mean drinks per episode 0.39 [I] and 0.40 [C] The intervention was more effective among women who drank more at study enrolment ($p<0.01$), and was more effective for the heavier-drinking subject	Whilst the study appears to be well run with no obvious flaws there appears to be a Hawthorne Effect. There are reductions in reported alcohol consumption in both the control and intervention groups. The impact of being in a study appears to be greater than the intervention. The intervention is complex and unlikely to be reproducible in many UK settings. Funded by grants from National Institute on Alcohol Abuse and Alcoholism

	median income was £4770 more than average median income for Massachusetts (the study area) in the study time period. Median gestation at enrolment: I 11wks, C 12 wks			when her partner was involved ($p<0.05$)	

First author, Year, Country	Study design, Quality	Study population Inclusion/ exclusion criteria Total participants, number randomised to each group Participant characteristics	Research question Power calculation Funding	Intervention Comparisons Length of follow-up, follow-up rate	Main results Only those reported by intervention group Effect size, CI	Confounders/ Comments
Reynolds 1995 USA	RCT 1-	Clients keeping a prenatal appointment at one of two public health clinics were screened Inclusion: women less than 25 weeks pregnant who reported drinking alcohol in the past month Exclusion: non-drinkers and women more than 25 weeks pregnant 78 recruited 42 intervention (Int), 36 usual care (Control) Charateristics (Int) (Control) African-American 69% 64% European-American 31% 36%	To test the hypothesis that low-income pregnant women randomised to receive a cognitive-behavioural, self-help intervention would have a higher alcohol quit rate than similar women who received usual care Power calculation not reported	The intervention group received a 10-minute educational session during the same clinic visit in which they had been recruited. During the session an educator described the effects of alcohol on the fetus and explained the use of a nine-step self-help manual to be completed at home in 9 days. The nine steps were: 1) fetal alcohol syndrome information – motivation to quit; 2) building self-efficacy to quit; 3) identifying the woman's drinking pattern using a diary; 4) removing alcohol and avoiding drinking locations; 5) finding a buddy and engaging social support; 6) self-monitoring and self-reward for quitting; 7)	A woman was coded as quitting if she reported having stopped drinking beer, wine, liquor and mixed drinks at the post test, 2 months after recruitment <u>quit rates</u> Int control All subjects 88% 69% p<0.058 African-American 91% 68% p<0.05 Other 80% 71% Income <$5000 89% 75% Income >$5000 87% 57% <0.10 < 7 drinks/ month 100% 71% <0.01 > 7 drinks/ month 73% 68%	The study is small and no power calculation is presented. 17 of the 78 women recruited scored as 'problem drinkers' at initial screening. These were given a list of treatment facilities, encouraged to obtain evaluation of their drinking, and retained in the study. The number of 'problem drinkers' randomised to each group is not reported A validated 'bogus pipeline' procedure was used (i.e. it was stated that blood and urine samples would be tested for alcohol) to address the potential

		income <$5,000 pa 56% 61% Weeks pregnant 13 12 Mean Drinks per month 44 28	Funding from the National Institute on Alcohol Abuse and Alcoholism	resisting interpersonal and media pressure to drink; 8) coping with stress without drinking; 9) maintaining abstinence. Intervention women received a follow-up phone call at one week to check progress Controls received the information on effects of alcohol and pregnancy routinely provided by the clinic including brief sessions with clinic staff and a video tape on prenatal care Length of follow-up: 2 months Follow-up rate: Intervention 39/42 (92.8%), Control 33/36 (91.6%)		criticism that self-report measures are open to social desirability bias

First author Year country	Study design Quality	Participants	Research question	Intervention measurement	Main results	Confounders/ Comments
Waterson and Murray-Lyon 1990 UK	Non-randomised controlled trial 2-	Women attending antenatal clinic West London Hospital between May 1982 and October 1983. All 2100 mothers were enrolled in the study. Two trials were undertaken Trial 1 Group 1 477 Group 2 559 Trial 2 Group 3 564 Group 4 500	To assess the impact upon drinking in pregnant women of basic advice on reducing drinking during pregnancy delivered using different methods	<u>Trial 1</u> Women in control group given a leaflet (group 1) Women in intervention group given leaflet, advice and reinforcement of advice from doctor (group 2) <u>Trial 2</u> Women in control given leaflet (group 3) Women in intervention group given leaflet, advice from doctor and watched a video (group 4) Women were given questionnaires about drinking behaviour before the intervention. Two follow-up questionnaires were at approximately 28th week and after delivery	Percentage of each group reporting alcohol consumption at baseline Group 1 39% Group 2 37% Group 3 34% Group 4 34% <u>Questionnaire follow-up</u> In trial 1 55% of the mothers completed questionnaire two and 74% completed three In trial 2 50% of mothers completed questionnaire two and 34% completed questionnaire three Outcomes in women drinking >7units per week before pregnancy. Success= reduced drinking Proportion classified as success Group 1 63% Group 2 68% Group 3 69% Group 4 66%	A similar proportion of controls and intervention group women reduced their reported alcohol consumption. No power calculation was presented but the numbers included in the study were quite large. The low return of questionnaires in trial 2 is a problem

7. a) What interventions are effective in increasing awareness and knowledge about food safety advice among pregnant women?

b) What interventions are effective in changing food safety practice among pregnant women?

Studies to be included	Evidence type	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review none Randomised trials none UK Studies none	The search strategy found no studies that had evaluated different ways of providing food safety advice to pregnant women. Given the importance of food safety during pregnancy this appears to be an area where research is required. A study from the USA was identified which indicated that warnings about the mercury content of some types of fish resulted in a fall in fish consumption (Oken E. Decline in fish consumption among pregnant women after a national mercury advisory. Obstet Gynecol 2003)). This weak evidence suggests that specific government warnings about the safety of a particular food result in a fall in consumption of that food.

8. What educational interventions that are aimed at all pregnant women are by themselves effective in improving dietary intake and nutritional status?

   What educational interventions that are targeted at a defined group of pregnant women, for example, low income or ethnic minorities are by themselves effective in improving their dietary intake and nutritional status?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic review</u> D'Souza 2005 Van Teijlingen1998 <u>Randomised trials</u> All trials included in the two systematic reviews <u>UK studies</u> Anderson 1995 Doyle 1992	The evidence comes from two systematic reviews which included studies using a range of interventions in different populations. Many of the included studies are of poor quality or are small. In both reviews the quality of the included studies are criticised. The applicability of the findings of most of the studies to UK women today is highly questionable for example, Hunt's study population was Mexican immigrants to the USA and was undertaken in 1976, Gray-Donald's study population was Cree Indians from Canada, Briley's study population was 27 African American women, and Kafatos' study population were women in rural Greece. The two UK studies probably provide the most relevant evidence and for these studies separate evidence tables are provided.	There is a lack of high quality evidence to answer these questions. In the few studies that have been published there are important variations in the interventions and populations studied. The evidence that does exist suggests that a brief intervention (Anderson's information packs) has an impact on knowledge but does not significantly improve nutrition and a more intense intervention (Doyle's counselling every three weeks during second and third trimester) might have a modest impact on birthweight. No study has robustly investigated the impact of educational interventions during the early stages of pregnancy.

First author, year	Research design Quality Level of evidence Inclusion/exclusion criteria	Review/Research question	Study Study Population	Intervention tested in study	Main results of the review	Applicability to the UK Confounders/ Comments
(D'Souza et al., 2005)	Systematic review 2+ Inclusion criteria Participants and settings: Studies of socially disadvantaged women of childbearing age in developed country settings. Interventions: food supplements or vouchers, income support exclusively for food purchase, nutrition education/ advice. Exclusion criteria Participants and settings: Studies of women needing special diet for medical reasons e.g. diabetes mellitus; studies	What is 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? To identify which components of existing programmes that aim to improve nutrition of childbearing women show signs of success. Effectiveness of nutrition education and/or counselling	8 studies of nutritional advice/ education/ counselling Briley et al. 2002 RCT 1- Doyle 1992 controlled trial 2+ Gray-Donald 2000 before after study Hunt 1976 RCT 1+ Kafatos 1989 group randomised trial 1- Long 2002	Briley – home visits, diet recall, nutrition advice, goal setting Doyle – dietary counselling – dietary counselling + supplements Gray-Donald- dietary counselling, cooking demonstrations, leaflets Hunt - Five nutrition education classes Kafatos - Nutrition information every 2 weeks from nurse after 20 weeks gestation, practical advice, written	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 Hunt 1976 and one Controlled trial Widga and Lewis 1999) 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 Hunt 1976) Nutrition education aimed at reducing the risk of gestational diabetes in a	The reviewers note that this section of the review included three RCTs, four nonrandomised controlled trials and one before-after study. That overall, variations in the characteristics of participants, study settings and quality were wide. and only 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. In addition to the above concerns of the reviewers it

	conducted in low-income countries. Interventions: Studies of effects of specific vitamin and mineral supplements		controlled trial 2- Sweeney 1985 RCT 1- Widga and Lewis 1999 controlled trial 2-	information Long – nutrition education curriculum and WIC Sweeney – nutrition assessment + protein prescription, counselling to take prescription Widga – nutritionist advice, written materials, support from significant other	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 Gray-Donald 2000) Nutrition counselling may have an impact on mean birth weight (moderately strong evidence from one Doyle 1992) 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 Gray-Donald 2000) Nutrition counselling probably has no impact on rates of low birth weight (moderately strong evidence from two controlled trials Doyle	is unclear the extent to which two of the studies that met some of the quality criteria are applicable to the UK. The Gray-Donald study population were Canadian Cree Indians and the Hunt study population was Mexican immigrants and the interventions were fashioned to meet their needs. The Sweeney study is an evaluation of a protein prescription and not education alone.

					1992, Widga 1999 and one before-after study Gray-Donald 2000) Nutrition counselling probably has no impact on gestational age at birth, newborn head circumference or length at birth (moderately strong evidence from two controlled trials Doyle 1992, Widga 1999 and one before-after study Gray-Donald 2000)	

First author, year	Research design Quality Level of evidence Inclusion/exclusion criteria	Review/Research question	Study Study Population	Intervention tested in study	Main results of the review	Applicability to the UK Confounders/ Comments
Van Teijlingen 1998	Systematic review 2+ Studies based on experimental or quasi-experimental designs i.e. RCTs, controlled before-and-after study (CBA) or an interrupted series analysis Only English language studies Exclusion criteria Women clinically at high risk of diet-related disease e.g. diabetes Studies where the aim was weight management in overweight subjects and not healthy eating per se (but did include interventions	What is the effectiveness of healthy eating interventions to promote healthy eating in women of childbearing age (and pregnant women)? Funded by the Health Education Authority (HEA)	3 studies of nutritional advice/ education/ counselling for pregnant women 1 study general advice and social support Sweeney 1985 RCT 1- Kafatos 1989 group randomised trial 1- Villar and Belizan 1992 1995 RCT Anderson 1995 Non-randomissed trial	Sweeney – nutrition assessment + protein prescription, counselling to take prescription Kafatos - Nutrition information every 2 weeks from nurse after 20 weeks gestation, practical advice, written information Villar and Belizan – not a Nutrition intervention, social support and advice about services Anderson – Information packs at	Women's knowledge – Only Anderson addressed this and found the intervention had a small but statistically significant impact. Intake of fat – Anderson and Kafatos measured this. Anderson found a small non significant difference favouring the intervention. Kafatos demonstrated differences of 10g a day during the third trimester. Intake of carbohydrates - Anderson and Kafatos measured this. Anderson found a small non significant difference favouring the intervention. Kafatos demonstrated differences of 30-60g a day during the third trimester.	The Sweeney study is an evaluation of a protein prescription and not education alone. The participants in the Kafatos study were rural Greek women and "most families derive a substantial part of their daily diet from home produce and domestic livestock" The authors of the study also note an important potential bias. "deliberate restriction of intake among women in the

	to prevent obesity in non-obese subjects). Therapeutic studies reporting for example the effect of supplementation with vitamins or other nutrients The review used the methods of the Cochrane Collaboration and the NHS Centre for Reviews and Dissemination. Searches were with Medline, Embase, CINAHL, the Cochrane Library database and health education/health promotion and social science databases from 1985. Hand searching was of key journals, reference lists from reports and consulting with relevant researchers and specialists.			booking and mailed at 26 weeks gestation	Intake of fibre – Anderson measured this and report a small but not significant increase in the intervention group Energy – Anderson, Kafatos and Sweeney measured this. Anderson found a small non significant difference favouring the intervention. Kafatos demonstrated differences of about 200 Kcal per day in favour of the intervention throughout the data collection period. Sweeney report a 189Kcal per day difference in favour of the intervention group. The review concludes that there is a dearth of research in this area that has been undertaken in the UK or applicable to a UK setting.	control group in anticipation of an easier delivery appears to have been a contributory factor in the contrary pattern of significantly lower mean daily intakes in this group during the third trimester”

First author Year country	Study design Quality	Participants	Research question	Intervention measurement	Main results	Confounders/ Comments
Anderson 1995 UK	Non-randomised controlled trial 2+	All women attending antenatal clinic Aberdeen Hospital Nov 87 to Oct 88. The control and intervention populations were selected according to their hospital registration numbers. 328 women were invited to take part, 164 intervention and 164 controls	To test the response of pregnant women to dietary advice by comparing nutrition knowledge, attitudinal variables to healthy eating and nutrient intake in women receiving routine care and women receiving a special educational intervention	Women in the control population received usual care which included nutrition advice. Women in the intervention group received usual care and also a first education pack from the midwife at study entry. They then received a second pack posted to them at 26 weeks gestation. At 30 weeks both groups were invited to fill in specific questionnaires about food knowledge and attitudes and	141 intervention group women completed the questionnaires and 145 control group women. Follow-up losses in both groups were for similar reasons which included, miscarriage, left the area. The characteristics of the two groups in terms of marital status, social class, parity and smoking were similar. The intervention group had more younger women <20 years than the control group (13% v 4%). <u>Knowledge scores (mean)</u> Intervention Control Nutrition terms 1.4 1.4 Theoretical principles 2.9 2.7 Practical applications 6.7 5.9* Total 10.9 10.0* * statistically significant <u>Attitude scores (mean)</u> Intervention Control Behavioural intention 1.8 1.7	This is a well run study and highlights an important difficulty with educational material alone. Educational interventions can often be shown to increase knowledge but this improvement in knowledge may not translate to a change in attitudes or behaviour.

				record their food intake	Direct attitudes 7.6 7.5 Direct subjective norm 0.6 0.4 Estimated attitude 19.4 17.7 No statistically significant differences 111 intervention group women and 113 control group women filled in a food diary Intervention Control Energy (kj) 9405 9489 Protein (g) 76.7 5.9 Fat (g) 97.9 100.0 Sugar (g) 112.1 112.8 Dietary fibre (g) 21.1 20.2 Alcohol (g) 1.3 1.1 No statistically significant differences There were also no differences between the groups for a wide range of minerals and vitamins The authors conclude that written information to pregnant women can improve knowledge about nutrition but does not improve diet	

First author Year country	Study design Quality	Participants	Research question	Intervention measurement	Main results	Confounders/ Comments
Doyle 1992 UK	Non-randomised controlled trial 2+	Women attending Salvation Army Mothers Hospital in East End London The control and intervention populations were selected on a rotating monthly system. There were 3 intervention arms and one control arm.		Women in the control population received no intervention and usual care All women in intervention group had 3 weekly dietary counselling during the second and third trimester. The intervention group were divided into three groups. Group 1 got counselling alone, group2 also go vitamin supplements and group 3 got counselling vitamin supplements and a supplement of linoleic acid.	Control all interventions Recruited 326 756 Drop outs 60 (18%) 123 (16%) Reasons for drop outs include moved away, miscarriages, multiple births 899 singleton births included; 633 counselled intervention group women 266 controls Control all interventions Number 266 633 Mean birthweight (g) 3192 3284* Maternal weight gain (kg) 11.9 12.3 Head circumference (cm) 34.1 34.3 Length (cm) 51 51.1 Gestation (days) 275 275 Births ≤ 2000g 7.5% 5.4% * statistically significant Comparison of different interventions Intervention Group 1 2 3 Number 217 211 205 Mean birthweight (g) 3266 3317 3268	The results presented indicate that counselling has a small but statistically significant impact on birthweight. The authors do not formally compare intervention group1, counselling alone to the control population but instead group all intervention women together. Two thirds of these women received nutritional supplements as well as counselling. The mean birthweight in the counselling alone group is higher (3266 v 3192) but this might not be statistically significant.

					Maternal weight gain (kg) 12.2 12.0 12.7 Head circumference (cm) 34.4 34.1 34.3 Length (cm) 51.0 51.1 51.0 Gestation (days) 274 276 274 Births ≤ 2000g 4.7% 3.8% 6.9% No differences in birth outcomes were found between those taking supplements and those receiving counselling only. Based on this study and the literature the authors conclude that birthweight and head size can be changed very little by dietary supplementation or counselling during the second and third trimester.	

9. Do interventions that include the provision of food, vouchers or incentives to buy specific foods, improve pregnancy outcomes and/or the dietary intakes and nutritional status of pregnant women?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	Systematic review D'Souza Randomised trials Metcoff 1985 UK studies none	The evidence to answer this question comes from evaluations of the WIC programme in the USA. The study by Metcoff compares two groups of women who were assigned as being at risk of low and high birthweight babies. The decision to exclude women believed to be likely to have a normal birthweight baby from the study is unusual but as it happened prior to randomisation it probably has not biased the findings. The large study by Rush has two flaws that might lead to important bias. The first is that a quarter of the control population enrolled in WIC and had to be excluded from the analysis. The impact of this self selection is unknown. The second is that information from hospital delivery records was unavailable for 25% of the study population. This study has therefore been graded with a minus to indicate these flaws.	It is unfortunate that the large evaluation of WIC undertaken by Rush and colleagues is compromised by non-compliance in the control groups. This non-compliance is understandable as women remaining as true controls were materially disadvantaged by having to forego benefits. The Metcoff study recruited women at mid-pregnancy and therefore offers no evidence about the impact of food support throughout a whole pregnancy. Whilst it is possible that the WIC programme produces important benefits for participants there is insufficient high quality evidence to demonstrate that this is the case.

Food support programmes for low income and socially disadvantaged childbearing women in developed countries: systematic review of the evidence

First author Year Country Study design Quality	**Study design and for SR no. and type of studies included in SR**	**Research question of the SR**	**SR inclusion/ exclusion criteria**	**Study Study aim Populations**	**Intervention Data collection**	**Main results**	**Confounders/ Comments**
D'Souza et al 2006 Systematic review 2+	SR Three studies (1 RCT and 2 non-RCT's) were included which evaluated the effectiveness of the USA's 'WIC' Programme -The Special Supplemental Nutrition Program for Women,	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	1. Studies of women in the childbearing age range were included, in particular of women socially disadvantaged by virtue of: income; age; ethnicity and area of residence. 2. If studies included high income women, they were	1. Metcoff al 1985 RCT USA 1+ Study aim To test the effect of WIC intervention from midpregnancy to term on birth weight especially in women identified as	Intervention group Received WIC Vouchers exchangeable for milk, eggs and cheese providing 40-50g/day protein and 900-1000kcal/day Control group Did not receive WIC vouchers. Data collection:	No significant differences between drop-outs and those remaining in study Characteristics of participants Ethnicity: 74% white; 21% black; 1% Native American; 4% Oriental or Mexican. Mean age: 21.9 +/- 4.4 years Mean years in education: 11.3+/-1.7 Primipara: 32.3% > 4 pregnancies: 16.6% Overweight by >20%: 26% Comparability of groups	Metcoff's study method is unusual in that the eligible population is divided into three groups based on predictions of eventual birth weight. The study therefore compares the impact of the WIC supplement on two groups of women of a higher risk of a small or large baby. The study reports an interesting observation that the WIC dietary supplements may have a positive impact on the birthweight of smokers. However this study was not designed to

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	Infants and Children: Metcoff et al 1985 (RCT) Rush et al 1988 (non-RCT – National Evaluation of WIC) **<u>WIC Program</u>** Is a USA federally funded programme for women, infants and	related to maternal and infant nutrition?	included only if separate results could be extracted for high and low income groups. 3. Studies were included where women were recruited during the peri-conceptual period, pregnancy, the post partum period, or the inter-pregnancy interval. 4. Studies	likely to have small or large babies. Biochemical data were also collected to test if the WIC intervention had an effect on maternal nutriture , including plasma nutrient levels and leukocyte protein synthesis. <u>Inclusion criteria</u> 824 pregnant women	included 24 hour dietary recall; maternal anthropometric measures; Plasma nutrients at 19+/- 2 weeks and 35+/- 2 weeks; birth outcomes including weight, length head circumference gestational age	No differences between control and intervention populations except that intervention group women weighed more at study entry than controls (p<0.007): **I:** 69kg.4+/-15.8kg **C:** 65.6kg +/- 14.7kg This was adjusted for in analysis Of the 471 women selected for inclusion 410 women were compared in the analysis <u>Pregnancy outcomes</u> Low birth weight (unadjusted) Intervention (n=238) 8.68 % Control (n=172) 6.9% (not significant) Birth weight (unadjusted for maternal weight at entry)) mean Intervention (n=238) 3254g Control (n= 172) 3163g p=0.039	investigate the impact of WIC on the size of babies born to heavy smokers. Therefore this observation should not be treated as strong evidence from an RCT.

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
	children on low income. There are three core elements: fixed value food vouchers; nutrition education and counselling; and referral to other healthcare and social services e.g. smoking cessation. Food vouchers are exchangeable for a		were included from developed countries only. 5. Studies from low /income developing countries were excluded, 6. Studies involving women with medical conditions resulting in special dietary needs, e.g. diabetes were excluded.	attending prenatal clinic at Oklahoma Memorial Hospital that were eligible for WIC (household income up to 185% poverty level) provided consent to take part. <u>Power calculation</u> Unclear – a pre-tested equation based on an earlier study <u>Selection of</u>		NB after adjusting for maternal weight at entry, effect of WIC on birth weights of all participants was not statistically significant Birth weight in babies of heavy smokers >10 cigarettes/day mean, Intervention (n=68) 3235g Control (n=53) 3059g p=0.017 <u>Maternal outcomes</u> Heavy smokers (>10 cigarettes/day) maternal weight at entry**.** Mean Intervention (n=68) 67.1kg Control (n=53) 67.5kg Mean difference in maternal weight at study entry (19 weeks) between Intervention and Control groups: +3.8kg in favour of Control group	

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	'basket' of foods rich in protein, calcium, iron, vitamins A and C and include: iron fortified breakfast cereal; fruit/vegetable juice; eggs; milk; cheese; peanut butter; dried peas/beans; tuna; carrots. Women may opt out of nutrition counselling			particiapnts Women were selected to participate in the study if they were predicted to have a baby of low birth weight or high birth weight. 471 active participants were randomised. A third group of women predicted to have average sized babies were also followed. Computer		Maternal weight at 36 weeks mean [SE] Intervention (n=208) 79.3kg [0.3] Control (n=145) 76.8kg[0.3] p=0.057 Mean bicep skin fold thickness (n) [SE] Intervention (n=199) 16.2mm [0.5] Group (n=142) 14.7mm [0.6] p=0.059 Conclusion After adjusting for baseline differences in maternal weight no significant difference was found in numbers of low birth weight babies born between intervention and control groups. After adjusting for baseline differences in maternal weight no	

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
	sessions. The WIC program and the contents of the food basket vary from State to State			randomised numbering used to assign women to Control (**C)** or Intervention (**I)** *g*roups		significant difference in mean birth weight between intervention and control groups In a sub set of smokers the intervention had a positive impact on birthweight.	
				<u>Rush et al 1988</u> Longitudinal cohort study USA 2- <u>Study aim</u> To compare the impact of the WIC	<u>Power calculation</u> Reported – three stage probability sampling design. Intended to yield 6,000 women.	<u>Diet outcomes</u> The WIC group reported an intake 133mg/d more calcium than controls at follow-up ($p<0.001$) The WIC group reported an intake 3.2 mg more iron than controls at follow-up ($p<0.001$) The WIC group reported an intake 32.4 mg more vitamin C than controls at follow-up	The Rush study's findings underestimate any benefits from participation in WIC because the authors report that approximately a quarter of the control population received some WIC benefits after enrolment.

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
				intervention on mother and offspring to that of no intervention in low income pregnant women <u>Inclusion/ exclusion criteria</u> Women from WIC centres and prenatal clinics in 48 states and District of Colombia. Both Intervention (**I)** and Control (**C)** groups recruited	<u>Intervention group</u> WIC food vouchers for breakfast cereal, vitamin C rich juice, milk, cheese, eggs, peanut butter and dried peas/beans. Nutrition counselling / education Referral to other healthcare and social services Individual care	(p<0.001) <u>Pregnancy outcomes</u> Low birth weight at follow up <2501g (adjusted) Intervention (n=2708) 5.7% WIC-Control (n=175) 4.2% Control (n=497) 6.8% (not significant0 Mean birth weight at follow up (adjusted) Intervention (n= 2708) 3292g WIC-Control (n=175) 3303g Control (n=497) 3285g (not significant) Duration gestation at follow up (adjusted) mean, Intervention (n=2708) 279 days WIC Control (n=175) 279.8 days Control (n=497) 279.3 days (not significant)	The hospital records of women and consequently their baby's size were only available for 75% of the women enrolled in the study. This substantially reduced the power of the study to detect any differences. In the final sample the power of this study to detect a difference of 30g in birth weight as a result of WIC participation at level of 0.05 was only 0.25. Although federally funded, WIC varies from State to State. There was a strong relationship between the quality of the programme

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
				before end 2nd trimester and **C** group at onset of prenatal care. Included if in 1st or 2nd trimester, **I** group eligible for and accepted by WIC, **C** group eligible but not accepted. Excluded if: diabetic, Native American or pregnant 6 months + **Characteristics**	plans <u>Control group</u> Were offered nutrition education/counselling at prenatal clinic. Plus Food Stamps, 'Aid to Families with Dependent Children' (AFDC) , Medicaid and vitamin and mineral supplements. NB – some **I** group were also in receipt of Food Stamps &	Pre-term births < 33 weeks Intervention 0.3% Control 0.9 % p = <0.05 WIC Control 0.11% Control 0.9% (not significant) Pre-term births< 37 weeks Intervention 9.4 % Control 12.7% (not significant) WIC Control 8.6% Control 12.7% (not significant) Mean head circumference Intervention 34.1cm Control 33.9 cm p=<0.05 WIC-Control 33.9 Control 33.9cm (not significant) <u>Maternal Outcomes</u>	(as assessed by Programme Managers) and: reduced rates of LBW (p<0.01), increased head circumference (p=<0.05) and accelerated foetal growth (p=<0.01)

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
				Ethnicity: Black 33.3% **I,** 21.6% **C;** Hispanic 15.9% **I,** 23.9% **C;** White non-Hispanic 48.2% **I** 50.4% **C;** Other 2.7% **I,** 4.1 %**, C.** Mean age (years): 22.23 I 22.6 C p=0.05 Education: <12 years - 55% I 48% C 12 years-	AFDC benefits <u>Data collection</u> included 24 hour dietary recall at entry and 36 weeks for 75% participants (reliability of the recall tested); 1 week food expenditure diaries; interviews for socio-demographic and behavioural information; anthropometri	Mean weight at entry adjusted for weight at conception: Intervention (n=3576) 65.17kg Control (n=601) 65.89kg p=<0.01 WIC-Control (n=216) 65.19kg Control (n=601) 65.89kg (not significant) Mean weight at follow up adjusted Intervention (n=3576) 72.17kg Control (n=598) 72.17kg WIC control (n=214) 71.86kg (not significant) Energy intake at follow up mean Intervention (n=2762) 2016.1 kcal/day Control (n=530) 1905.3 kcal/day p= <0.01 WIC- Control (n=181) 2047.4 kcal/day Control (n= 530) 1905.3kcal/day	

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
				34.1% I 38.4% C >12 years- 10.9% I 13.6% C Family income: < $3000 16.3% I, 10.8% C; $3000 -6999 31.8% I 26% C; $7000 – 12,999 25.6% I, 34.3% C; > $13,000 9.9% I, 12.6% C Primparas: 44.9% I 46.9% C (not significant) Previous LBW	c measures; birth and pregnancy outcomes. **Losses:** At late pregnancy follow up 21% (n=1112) **I** group and 77% (n= 1043) **C** group. ¼ of the **C** group had registered in WIC and data for this group analysed as a sub set 'WIC-control'. They were less affluent than the remaining	p=<0.05 Energy intake in control group decreased by 100kcal/day by end of pregnancy. Protein intake at follow up mean Intervention(n= 2762) 80.76g/day Control (n=530) 75.54g/day p=<0.01 WIC-Control (n=181) 81.82g/day Control (n=530) 75.54g/day (not significant) <u>Conclusions</u>: The intervention group had more favourable levels of calcium, iron and vitamin C No significant difference found in numbers of low birth weight babies born between groups No significant difference found in	

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
				21.6% I 18.8% C p=<0.05 Comparability Controls more affluent and privileged on almost all criteria	**C** group. For Birth outcomes, **I** lost 26% (n=1342) **C** lost 22% (n=300)	mean birth weight between groups No significant differences found in gestational age between groups A significant reduction was found in numbers of early pre-term births(<33weeks), but not in pre term births, 37 weeks in intervention group A significant increase in head circumference was found in the Intervention group Significantly higher energy intakes were found in mothers receiving WIC (Intervention and WIC control group) Significantly higher protein intakes were found in the intervention group	

First author Year Country Study design Quality	Study design and for SR no. and type of studies included in SR	Research question of the SR	SR inclusion/ exclusion criteria	Study Study aim Populations	Intervention Data collection	Main results	Confounders/ Comments
						Maternal weight gain was significantly higher in the intervention group.	

9. b) What interventions either by themselves or in addition to counselling and educational support are effective in improving the dietary intake and nutritional status of pregnant women?

Food support programmes for low income and socially disadvantaged childbearing women in developed countries: systematic review of the evidence

First author Year Country Study design Quality	**Study Design and For SR no. and type of studies included in SR**	**Research question of the SR**	**SR inclusion/ exclusion criteria**	**Study population**	**Intervention(s)**	**Main results**	**Confounders/ comment**
D'Souza et al 2006 Systematic review 2+	SR 2 RCT's based in the USA , Grahams et al 1992 and Olds et al 1986, were included which considered complex health and social care interventions which had at least one nutrition component. Both studies involved the use of home visits which provided social or psychosocial	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	1. Studies of women in the childbearing age range were included, in particular of women socially disadvantaged by virtue of: income; age; ethnicity and area of residence. 2. If studies included high income women, they were included only if separate results could be extracted for high and low income groups. 3. Studies were	**Graham et al 1992** **RCT** **USA** **1+** **Inclusion/ exclusion criteria** African American Women attending prenatal clinic at MacDonald Hospital for Women (University Hospitals of Cleveland, Ohio) May 1987 and May 1988. Included if: 17-28	**Research question** Can screening for poor pregnancy outcomes and intervention with high risk, inner city black women improve pregnancy outcomes? Sub questions: -Do high risk women receiving a home based intervention differ from those who do not? - Does home intervention effect use of prenatal care? Does pre-natal care affect the rate of low	Rate Low Birth Weight **%** Control group had no home visits Number % low 53 7.5 Intervention group Some home visits Number % low 62 12.9 Intervention group 4 home visits Number % low 52 7.7	The intervention was delivered after the 17th week and was one particular type of intervention. The transferability of the findings of this study to other populations and other types of home visiting interventions is questionable.

	support, encouraged participation in other services such as smoking cessation, or WIC and provided nutrition education as a substantial element of the intervention.	nutrition?	included where women were recruited during the peri-conceptual period, pregnancy, the post partum period, or the inter-pregnancy interval. 4. Studies were included from developed countries only. 5. Studies from low /income developing countries were were excluded, 6. Studies involving women with medical conditions resulting in special dietary needs, e.g. diabetes were excluded.	weeks pregnant ; 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 prior to registration Optional additional inclusion criteria: Smoker; Low maternal height /weight ratio; >27 years of age; Previous LBW baby Exclusion criteria: >28 weeks pregnancy; Living outside 5 mile radius of hospital. **Characteristics** Age: Mean 24 years Aged 14-19: 21% Aged >35: 4% Married: 11% Primiparous: 38%	birth weight? -Can a screening tool that takes account of social psychological and medical conditions predict which pregnant women will deliver a LBW baby better than one using medical information? **Randomization** By odd versus even numbering from a large table of digits **Power calculation** Reported – intended to yield sample size of 154 **Intervention group** (n= 87) In addition to usual care received: 'Peer' type home visitors, trained to deliver the intervention, provided the following at the participants home: - Psychosocial support and encouragement to	p=0.98 **Conclusion** **No significant difference found in the rates of low birth weight between intervention and control groups.**	

				Mean duration of pregnancy at registration: 18.5 weeks Used Medicaid: 84% % on Medicaid: **I** 93.1% **C** 74.5% p<0.01 **Comparability** Medicaid was used by significantly more of the Intervention group. This was the only variable reported by group.	the family to increase support to the mother, to be present for the home visit, clinic visits, maternity classes and delivery; Efforts to reduce family stress by referral to community services and acting as an advocate when needed; Information about health risks of smoking and alcohol and referral to groups for cessation; - Increased awareness of community resources; - Nutrition education and information about prenatal care and birth; - a small gift at each visit **Control group** (n=58) Routine care by the prenatal clinic **Data Collection** Questionnaire containing medical		

					and psychosocial questions Hospital records Outcomes recorded included: LBW; number of prenatal visits; efficacy of screening. No dietary assessment was reported. **Losses** Control 0 Intervention 24 of which: 7 refused intervention; 11 unable to contact; 5 transferred care; 1 miscarried		
				Olds et al 1986 RCT USA 1- Inclusion/ exclusion Criteria Study targeted black American and young single mothers recruited from antenatal clinics and private obstetricians	Research aim To evaluate a comprehensive programme of pre-natal and postpartum nurse home visitation. Randomisation Subjects drew their randomisation from a pack of cards. Packs were specific for race, marital status, ethnicity and area of residence	<u>Pregnancy outcomes</u> Mean birth weight babies born to all women adjusted (n) Intervention G3& 4 (166) 3285g Controls G1& 2 (142) 3262g	Olds study is a four armed trial with complex interventions including efforts to give up smoking, nutrition counselling and practical help to pregnant women. The findings of this study need to

				practices, Planned Parenthood and public schools in a deprived semi-rural county of the Appalachian region of New York State between April 1978 and Sept 1980. Included if: No previous live births; aged <19 years; single parent; low Socio economic status; <25 weeks pregnant. Excluded if > 25 weeks pregnancy Characteristics 4 groups of participants. Groups 1& 2 n= 165 Groups 3& 4 n= 189 Mean age (years): G1& 2 19.57 G3& 4 19.53 Diff 0.04 95% CI +/- 0.66 Proportion Social class IV & V:	Power calculation Not reported Intervention Group 1 (Control) Health & developmental screening for the child at age 1 and 2 years Group 2 (Control) Health & developmental screening for the child at age 1 and 2 years plus free transportation to regular prenatal and well child clinics Group 3 (Intervention) Health & developmental screening for the child at age 1 and 2 years plus free transportation to regular prenatal and well child clinics plus prenatal nurse home visits Group 4 (Intervention) Health &	Diff 23 95% CI +/- 134 Mean birth weight babies born to 14-16 year olds adjusted (n) Intervention G3 & 4 (28) 3423g Controls G1 & 2 (17) 3028g Diff 395 95% CI +/- 343 Mean birth weight babies of smokers (>5 cigarettes/day) adjusted (n) Intervention G3 & 4 (78) 3331g Controls G1 & 2 (64) 3235g Diff 96 95% CI +/- 177	be treated with some caution because the study does not present a power calculation. Many of the group sizes are small and the sub-group analysis is based on small numbers

				G1& 2 0.61 G3& 4 0.61 Diff 0.00 95% CI +/-0.10 Proportion married: G1& 2 0.43 G3& 4 0.41 Diff 0.02 95% CI +/- 0.10 Education (years): G1& 2 11.21 G3& 4 11.34 Diff -0.13 95% CI +/- 0.32 Weeks pregnant at registration: G1& 2 17.12 G3& 4 17.44 Diff -0.32 95% CI +/- 1.01 Pre-pregnancy weight (kg): G1& 2 59.08 G3& 4 59.65 Diff-1.24 95% CI +/-6.2	developmental screening for the child at age 1 and 2 years plus free transportation to regular prenatal and well child clinics plus prenatal nurse home visits plus nurse home visits during child's first two years. An average of 9 home visits made during each pregnancy. Home spanned prenatal period and until child from the first pregnancy was 2 years old. Visits encouraged prenatal social support; participation in other services including WIC; over 2/3rd of visit time was spent on nutrition education. Data collection Included birth weight; use of services Smoking habit; 24 hour dietary recall Interviews at entry	Low birth weight babies (<2500g) born to all mothers adjusted (n) Intervention G3 & 4 (166) 5.78 % Controls (142) 2.61 % Diff 3.17 95% CI +/- 4.01 Low birth weight babies (<2500g) born to smokers adjusted (n) Intervention G3 & G4 (78) 1.46% Controls G1 & G2 (64) 3.79% Diff -2.33 95% CI +/-4.12 Preterm delivery of	

				Cigarette/day G1& 2 6.94 G3& 4 7.65 Diff -0.71 95% CI +/-1.97 Dietary adequacy (% RDA 12 nutrients): G1& 2 72.46 G3& 4 69.34 Diff 3.12 95% CI +/-3.77 No helpers/kin: G1& 2 3.22 G3 & 4 2.86 Diff 0.36 95% CI +/-0.41 p <0.10 Comparability Greater dietary adequacy in the and less cigarettes/day in the intervention group than the controls Significant difference in no of kin/helpers and confidence of someone to accompany them in labour in nurse	and 32 weeks Losses Intervention G3 & 4 n= 12 Controls G1 & 2 N=14 Reasons for drop out moved or miscarried Women who dropped out from intervention group found to have significantly greater sense of control, over their lives and higher education	all mothers (n) Intervention G3& 4 (166) 6.90% Controls G1& 2 (142) 7.27% Diff -0.37 95% CI 2.30 Preterm delivery in smokers (n) Intervention G3 & 4 (78) 2.08 Controls G1 & 2 (64) 9.81 Diff 7.73 95% CI +/- 7.05 p<0.05 Maternal outcomes Number nutrition supplement vouchers (WIC) used at time of 2nd	

				visited group.		interview (n) mean Intervention G3 & 4 (152) 2.18 Controls G1& G2 (136) 1.56 Diff -0.62 95% CI +/- 0.55 p<0.05 Maternal weight gain at last visit from pre pregnancy weight (n) mean Intervention G3 & 4 (153) 16.2kg Controls G1& 2 (136) 14.9kg Diff -1.33 95% CI +/- 1.42 Maternal dietary	

						adequacy at 32 weeks (n) mean Intervention G3 & 4 (138) 73.86% Controls G1 & 2 (115) 71.75% Diff 4.47 95% CI +/- 4.38 p<0.05 Difference in cigarettes/day between entry and 2nd visit (n) mean Intervention G3 & 4 (77) -2.54 Controls (64) 1.63 Diff 4.17 95% CI +/-	

						1.01 p<0.001 <u>Conclusions</u> No significant difference in the mean birth weight of babies born to women in the intervention and control groups No significant difference in the rates of low birth weight between intervention and control groups Significantly lower rates of premature delivery in smokers in the intervention groups Significantly greater use of WIC vouchers in the intervention group No significant difference in maternal weight	

						gain between intervention and control groups Maternal diet significantly more adequate on a score of 12 nutrients in the intervention group Significantly more women stopped smoking in the intervention group	

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