Appendix F

Review 1: Preconception Evidence Tables

Evidence is presented to answer the following questions:

1. What interventions are effective in increasing knowledge of the recommended intake of folate and folic acid among women of child bearing age who are planning a pregnancy or might become pregnant?

2. What interventions are effective in increasing uptake of folic acid supplements in women of child bearing age who are planning a pregnancy or might become pregnant?

3. What interventions are effective in increasing dietary folate in women of child bearing age who are planning a pregnancy or might become pregnant?

4. What interventions are effective in increasing health professional's knowledge and awareness of the recommendations for folate and folic acid in women of child bearing age who are planning a pregnancy or who might become pregnant?

5. What interventions (other than those about folate or folic acid) improve nutritional status of women of child bearing age who are planning a pregnancy or might become pregnant?

Studies that are included for answering questions 1, 2, 3, and 5 are those in which an intervention was provided for women who were not known to be pregnant. Studies that evaluate the benefits of interventions for women already known to be pregnant are reported in the pregnancy review evidence tables. In addition to the evidence presented to answer these four questions some other relevant non-intervention studies undertaken in the UK are included which can be found at the end of each section.

1. **What interventions are effective in increasing knowledge of the recommended intake of folate and folic acid among women of child bearing age who are planning a pregnancy or might become pregnant?**

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic reviews</u> None <u>Randomised trial</u> Watson 1999, 2001 <u>Evaluations of UK Campaigns</u> HEA folic acid campaign 1995-1998 <u>Additional UK studies</u> Pearson, 1996	The Watson study was a well conducted randomised community intervention trial conducted in Australia and the HEA campaign is a public health campaign that was evaluated using appropriate methods.	Undertaking randomised trials of interventions to increase public awareness is difficult because of possible contamination between control and intervention groups. It is therefore not surprising that only one community randomised trial was found. The HEA campaign was the first national multi-intervention campaign, which has been comprehensively evaluated and offers information from the UK during the mid to late 1990s.

Evidence Tables

Folate and folic acid

First author and date	Study design, setting, 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
Watson 1999 and Watson 2001	Community (cluster randomised trial) and 3-year follow-up paper Australia 1+	Six geographically distinct Local Government Areas (LGAs) (total population 442,000) in Victoria, Australia. Within these LGAs 25% were women of childbearing age (15-44y). The LGAs were pair-matched on numbers of births per annum, % women of non-English speaking background, size, rural/ metropolitan status, socio-demographic profile and geographic isolation from other potentially selected LGAs. One of each pair was randomised to the intervention. Telephone surveys of women 15-44y (from random current list of telephone numbers in the 6 LGAs) were undertaken before and after the intervention. Characteristics of women	To determine the effect of an information campaign to increase knowledge of folate for the prevention of neural tube defects among women of child-bearing age, and to measure women's recall of sources of information and knowledge about folate The objective of the 3-year follow-up was to establish whether a previously observed increase in knowledge of the role of folate persisted in the intervention group	Intervention materials comprised an A3 poster, an A5 leaflet, a fridge magnet and a more detailed information kit on four sides of A4. The intervention material contained recommendations for actions for risk reduction for NTDs (take 0.5 mg folic acid tablets, choose foods rich in/ fortified with folate), under the slogan 'Folate for Women-Folate before Pregnancy'. The materials were delivered to a wide range of locations	Aware of association between folate and NTD **Before intervention (n=1197)** Overall estimate of awareness in control and intervention group (12%) Variation of awareness with age: <25y 5%, 25-34y 19%, 35+y 12%; p=0.001 By occupation: professional more aware, 20%; p=0.03) **After intervention (n=1206)** Overall awareness 20% Background awareness increased by 3.4% in control communities (p=0.02) A further 4% increase in intervention communities [odds ratio =1.33-1.42, p=0.001]. Variation by age and	The intervention was effective in increasing awareness but awareness was very low at the start of the campaign. The impact of this intervention on a UK population may be different because of a difference in baseline awareness. This intervention increased awareness but at the end of the campaign in 1997 only 20% of women correctly answered the question on the link between folate and spina bifida.

First author and date	Study design, setting, 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
		surveyed (n=2403) were similar at the two survey times for country of birth (Australia 89%, English-speaking country 5%, non-English-speaking country 6%); marital status (married 55%, never married 32%, other 13%); education level (<12y 44%, 12y 27%, trade/ other certificate 8%, tertiary 21%) and age (15-24y 28%, 25-34y 44%, 35-44y 28%) but not for occupational status (professional 23% and other paid employment 11% at both points; clerical 25% before/ 27% after, sales 23% before/ 19% after, not in paid employment 19% before and 24% after, p=0.01) A follow-up survey was undertaken at 3 years (n=1229)	Sample size needed to detect a doubling of the proportion aware from 14% to 28% (α=0.05, two-sided, 1-β=0.80), with use of matched pairs and randomisation by group required 200 in each LGA (1200 before and after the intervention, 2400 overall)	where women of childbearing age were expected to read it Baseline survey Nov-Dec 1996 Intervention late July-early October 1997 (2+ months) Follow-up surveys Nov-Dec 1997 and March-April 2000	occupation similar, except that a lower proportion of women 15-24y were folate aware after the intervention than before In the intervention group, 70% of women who were folate-aware knew the correct timing. Four times as many women remembered seeing the leaflet than the poster or information kit. The leaflet was distributed mainly at supermarket checkouts Awareness of association between folate and NTD in the 3-year follow-up: Overall awareness 30% (p<0.001) There was a significant general background increase in awareness but awareness in the intervention group remained 3.3% higher at three years than in the control population.	The study suggests that leaflets are better remembered by target group women than posters.

First author and date	Study design, setting, type and quality	Study population	Research question Power calculation	Intervention Comparisons Length of follow-up, follow-up rate	Main results Only those reported by intervention group Effect size, CI	Comment Funding
The Health Education Authority Folic Acid Campaign 1995-1998. HEA, 1998	Before and after surveys of random representative samples of women 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 raising 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	Advertising A range of media and public relations activities Creation and distribution of leaflets and posters. Provision of a free-phone advice line. Campaign ran for three years from 1995-1998 A series of representative national sample surveys. A representative national sample of women were interviewed before the campaign began in 1995. New surveys were repeated in 1996,1997, and 1998	Spontaneous awareness of folic acid as important to pregnancy 1995 1996 1997 1998 n=2070 n=508 n=617 n=473 9% 27% 39% 49% Prompted awareness of folic acid as important to pregnancy 1995 1996 1997 1998 n=2070 n=508 n=617 n=473 51% 66% 84% 89%	The method of evaluation was appropriate. The multi-intervention strategy used was effective. It is not possible to know which part of the campaign had most impact. Even after this large-scale campaign less than 50% of women were spontaneously aware of the importance of folic acid. £2.3 million national public education campaign

Additional Evidence

First author and date	Study design, setting, type and quality	Study population	Research question Power calculation	Intervention Comparisons	Main results Effect size, CI	Comment Quality
Pearson S, Ford F, Fraser R 1996	Cross-sectional questionnaire survey 3 -	Never-pregnant clients and staff of three large family planning clinics in Sheffield Recruitment of participants is not clearly explained. 60 client questionnaires were completed Mean age 20.1 years In full time education 26 White 56% 16 questionnaires were completed by staff Mean age 43.4 years Mean years experience since qualifying as doctor or nurse 20 White 16 (all)	To assess knowledge of current general nutritional guidelines and government directives about pregnancy nutrition. No sample size calculation is presented and the statistically tests knowledge in the never pregnant women to knowledge in the health workers.	The participants were given a nutrition survey that was previously piloted and validated	35 women in the client group were less than 17 years old Client n=60 / Professionals n=16 Need for folic acid 12% / 69% <u>Avoid</u> Alcohol 55% / 69% vitamin A (retinol) 3% / 63% blue cheese 35% / 63% liver 27% / 100% rare meat 55% / 88%	The study makes a strange comparison between knowledge in older professional heath workers and that of young non-pregnant women. The sample chosen makes it difficult to draw any generalisations from the study.

2. What interventions are effective in increasing uptake of folic acid supplements in non-pregnant women of child bearing age who are planning a pregnancy or might become pregnant?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic review</u> Ray 2004 <u>Randomised trial</u> Robins 2005 <u>Evaluations of UK Campaigns</u> HEA folic acid campaign 1995-1998 (in Ray 2004) <u>Additional UK studies</u> Mathews 1999	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 systematic review focussed mainly on providing estimates of uptake of folic acid but also assessed campaigns of folic acid awareness.	Numerous studies have evaluated folic acid and its benefit for unborn children is accepted. Therefore it is no longer ethical to run studies with control populations that receive no information about this benefit. This makes it difficult to evaluate interventions that are designed to increase intake of folic acid using an RCT design. Directly observing and measuring the intake of folate or folic acid in women who might become pregnant is also problematic and for practical reasons studies rely on reporting of intake or proxy measures such as prescription rates or changes in sales of folic acid supplements.

Evidence Tables

Folic acid supplements

First author and date	Study design, quality	Inclusion criteria for studies	Research question	Studies Interventions Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Funding
Ray 2004	Systematic Review 2+	Survey studies that evaluated the rate of folic acid or multivitamin supplement use, either before conception or in early pregnancy. Each study's definition of pre-conceptional or peri-conceptional folic acid used was used but there was an assumption that, for the latter, peri-conceptual use was the same as pre-conceptional use, unless otherwise specified. Exclusion criteria Studies that evaluated women at high risk of NTDs, in which ≥50% were taking an anticonvulsant drug,	To establish the rate of folic acid supplement use pre- and peri-conceptionally. Identify the characteristics associated with low rates of use Assess whether folic acid awareness campaigns are associated with higher folic acid use.	4 studies evaluated the change in peri-conceptional folic acid use following widespread mass media health campaigns: HEA campaign in UK 1996 • To increase public and professional's awareness of and access to folic acid fortified foods and supplements • TV & magazines Van der Pal-de-Bruin 2000 (Netherlands) Dutch 'Folic Acid Campaign' 1995 • For women wishing to conceive 'planners', 'future planners' and their health care professionals • Media aimed at public and professionals • Personal letters to professionals	<u>Impact of campaigns</u> Proportion of women reporting folic acid tablet use before and after the intervention Study — Before Number (%) — After Number (%) HEA, UK 71/262 (27) 36/75 (48) Netherlands 2000 78/1636 (5) 339/1612 (21) Netherlands 2002 17/342 (5) 161/452 (36) Australia 2001 50/187 27) 161/452 (46) In each study reported folic acid use significantly increased. The range of the before and after rate ratios was 1.7 to 7.2. Campaigns in the Netherlands were very successful in increasing use but prior to the intervention few women reported using folic acid and after the intervention the proportion using folic acid was only 36%. In	This systematic review also reports folic acid supplement intake in women prior to conception in different countries. The lowest rate (0.9%) was found in women southern Israel in 1999 and the highest rate (49%) was found in women in Vancouver, Canada in 1999. This substantial geographical variation in baseline use and knowledge about folic acid

First author and date	Study design, quality	Inclusion criteria for studies	Research question	Studies Interventions Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Funding
		had pre-pregnancy diabetes or had a fetal NTD in a previous pregnancy. Search of Medline, Embase and Nutriotiongate (CABI Publishing, Wallingford UK) databases 1990-2003. Hand searching was carried out of all retrieved research and review articles in all languages and authors contacted where necessary. There were no quality criteria for the selection of studies		De Walle 2002 (Netherlands) Dutch 'Folic Acid Campaign' 1995, 3 years later • Special attention paid to women of lower socio-economic status Chan 2001 (South Australia) 'Folate Before Pregnancy' campaign 1995 Telephone messages, leaflets, newspaper messages, occasional TV announcements	no study was the post-campaign rate of folic acid supplement use >50%. This study also reports that 30 studies considered the features that are associated with low peri-conceptional folic acid use. Lower level of formal education, immigrant status, young maternal age, lack of a partner and unplanned pregnancy were often associated with a more than 50% reduced odds of using folic acid.	supplements must be considered when assessing interventions to increase usage. It is important to note that even after widespread awareness campaigns many target group women do not take folic acid supplements Funded by the Physicians' Services Foundation of Ontario, Canada

First author and date	Study design, setting, 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	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 gynaecological 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 intentions, folic acid awareness or preventive health behaviours	To determine the impact of a physician intervention during routine gynaecologic 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 gynaecologist, 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. Follow up: The intervention was evaluated by follow-up telephone calls 2 months later using standard	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 of folic acid than among the whole sample	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. A non-randomised but well run study by de Weerd (Preconception

First author and date	Study design, setting, 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
				questions about intake of folic acid and vitamins. Follow-up rate 87%.		counselling 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.

First author and date	Study design, 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
The Health Education Authority Folic Acid Campaign 1995-1998. HEA, 1998	Before and after monitoring of a public health intervention in the UK 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 free-phone 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	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.

Additional Evidence

First author and date	Study design, setting, type and quality	Study population	Research question Power calculation	Intervention	Main results Effect size, CI	Comment Quality Funding
Mathews et al 1998	Prospective cohort survey 3+	Randomly selected primigravidae Caucasian women recruited from antenatal booking clinics at a district hospital in the South of England. Inclusion criteria were healthy women with normal pregnancy and no history of miscarriage, or termination due to neural tube defect and no family history of NTD Women were recruited between May 1994 and February 1996 Sample size n = 963 Dietary data from 640	To examine the prevalence of folic acid supplementation prior to conception and in the first trimester of pregnancy, and to identify socio-demographic variables associated with the use of supplements	Structured interviews with the women were conducted at trained interviews at the clinic. At the time of the interview 90% of the women were between 14 and 17 weeks gestation, and all were between 9 and 20 weeks	31.5% (95% CI 28.5 – 34.4) of pregnant women reported using supplements containing folic acid prior to conception The proportion of women using pre-conceptional folic acid increased by approximately 1% per month during 22 months of the study. 38.1% of women began taking folic acid only after confirmation of the pregnancy and that proportion was constant over time. Use of folic acid supplements before pregnancy and in the first trimester was positively related to maternal age, education, social class and living with a partner ($p<0.001$ for all variables). Women who smoked were less likely to take supplements than non smokers ($p <0.001$)	This study again shows that during the 1990's many target group women do not take folic acid during the peri-conceptual period.

First author and date	Study design, setting, type and quality	Study population	Research question Power calculation	Intervention	Main results Effect size, CI	Comment Quality Funding
					The lowest use of supplements was among women who were single, had low levels of education, were young and who smoked.	

3. What interventions are effective in increasing dietary folate in women of child bearing age who are planning a pregnancy or might become pregnant?

Studies to be included	Evidence type	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic review</u> None <u>Randomised trials</u> Ortega 2006 <u>Additional UK studies</u> Elkin 2000	No UK studies were identified that measured dietary folate consumption before and after an intervention. This lack of studies probably reflects difficulties in recruiting an appropriate study population and measuring folate consumption. Two studies of interest were identified. The first was a small study undertaken in Ireland, Cuskelly et al. Effect of increasing dietary folate on red-cell folate: implications for prevention of neural tube defects, Lancet 1996. This study included 41 women. Red-cell folate concentrations increased significantly over the 3 months in the groups taking folic acid supplements or food fortified with folic acid ($p<0{\cdot}01$ for both groups). By contrast, although aggressive intervention with dietary folate or dietary advice significantly increased intake of food folate ($p<0{\cdot}001$ and $p<0{\cdot}05$, respectively), there was no significant change in folate status. The second study was undertaken in the Netherlands, Brouwer et al. Dietary folate from vegetables and citrus fruit decreases plasma homocysteine concentrations in humans a dietary controlled trial, Journal of Nutrition 1999. This study found that under controlled conditions with a diet rich in vegetables and citrus fruit it was possible to increase folate status. The difference in results from the two studies is probably explained by differences in design and compliance to protocols. It is uncertain if strict adherence to dietary advice by individuals is sufficient to reduce the incidence of neural tube defects but it is unlikely that whole populations would all be able stick to a strict diet. The National Diet and Nutrition Survey of Adults 19-64 (Henderson 2003; Rushton 2004) reports that only 8-16% of women aged 19 to 49 years reached intakes from food and supplements of 400µg, the level recommended by the Department of Health.

First author and date	Study design, setting, 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
Ortega 2006	RCT 1-	Participants were recruited via advertisements targeted at university students Inclusion criteria: Female Age 20-35y Healthy BMI 24-35 kg/m^2 Had not quit smoking in the past 2 months Not currently involved in weight loss programme Had not lost more than 4.5 kg in the past 2 months Had not lost or gained more than 3 kg between the first interview and the start of the study Regular menstrual cycle No more than 2 alcoholic drinks per day Not pregnant or lactating 67 of the 193 volunteers met the inclusion criteria Participant characteristics reported for those who	To determine the folate status of a group of overweight/ obese young women and to analyse the changes produced by following two slightly hypocaloric diets, one rich in vegetables, the other rich in cereals, especially fortified breakfast cereals Power calculation not reported	Diet V Energy-rich foods restricted (to 80% of requirements[1]). Vegetables increased (minimum x3 per day) Diet C Energy-rich foods restricted (to 80% of requirements[1]). Cereals increased. Breakfast cereals (fortified with folic acid) recommended x3 per day, and subjects advised to eat other cereals (bread, rice, pasta etc)	**Dietary folate** *Folate* (µg/dl) Mean [SD] Diet V Diet C Pre-intervention 224.3[69.9] 269.6[77.1] n=36 n=31 p<0.05 2 weeks 337.1[114.2] 544.9[120.8] p<0.001 6 weeks 418.4[115.9] 533.6[103.1] n=28 n=29 p<0.001 *Folate density* (µg/MJ) Mean [SD] Diet V Diet C Pre-intervention 25.9 [6.8] 28.4 [10.1] n=36 n=31 2 weeks 51.8 [16.7] 83.2 [15.9] n=32 n=29 p<0.001 6 weeks 64.5 [19.6] 80.9 [17.6] n=28 n=29 p<0.01 *Folate intakes* <RI (%) Diet V Diet C Pre-intervention 97.2 (n=36) 93.5 (n=31) 2 weeks 75 (n=32) 6.89 (n=29) p<0.001 6 weeks 46.4 (n=28) 13.8 (n=29) p<0.01 *Folate intakes* <67% RI (%) Diet V Diet C Pre-intervention 72.2 (n=36) 54.8 (n=31) 2 weeks 21.9 (n=32) 0 (n=29) p<0.01 6 weeks 7.14 (n=28) 0 (n=29) **Serum folate** (nmol/l) mean [SD] Diet V Diet C	Paper reports some 11.1% of V subjects and 9.7% of C subjects (NS) declared taking supplements containing folic acid on a sporadic basis. Similarly 41.7% of V subjects and 41.9% of C subjects (NS) declared taking foods fortified with folic acid. No significant differences were found at baseline in serum folate concentrations of those who had taken or not taken supplements or fortified foods

First author and date	Study design, setting, 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
		completed the study (n=57) Paper states most were university students Diet V (n=36) Diet C (n=31) Mean weight (kg)[SD] 73.3[7.7] 77.8[10.9] Mean height (cm)[SD] 161.8[5.0] 164.8 [5.9] P<0.05 Mean BMI (kg/m^2)[SD] 28.0[2.8] 28.6[3.6]		Folate intake (as dietary folate equivalents[2] (DFE)) Serum folate Follow up at 2 weeks and 6 weeks 57/67 women completed the 6-week dietary intervention period (85%)	Pre-intervention (n=35) 16.9 [8.5] (n=31) 18.4 [15.1] 2 weeks (n=29) 20.8 [10.5] (n=30) 30.5 [15.5] p<0.01 6 weeks (n=27) 21.0 [7.9] (n=27) 32.9 [15.1] p<0.001 **Weight loss during study** (kg) Mean [SD} Diet V Diet C 2 weeks (n=32) 0.9 [0.6] (n=30) 1.5 [0.9] p<0.01 6 weeks (n=28) 2.0 [1.3] (n=29) 2.8 [1.4] p<0.05 Other results are reported Researchers conclude breakfast cereals may be of special help with respect to folate status in overweight/obese young women following energy restriction diets	Paper states allocation to the diet groups was randomised. Method of randomisation not described Funding by Kellogg España via the Universidad-Empresa project 362/2003

[1] Theoretical energy expenditure was established by taking into account the body weight, age and physical activity of all subjects, using equations proposed by the World Health Organisation (in: World Health Organisation (1985) *Methodology of Nutrition Surveillance. Physical condition: Use and Interpretation of Anthropometric Data. Report of a Joint FAO/UNICEF/WHO Expert Consultation.* Technical Report Series no. 854. Geneva: WHO.

[2] Paper states 1 DFE = 1µg food folate = 0.6µg folic acid from fortified food (Food and Nutrition Board and Institute of Medicine (2000) *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline.* Washington, DC: National Academy Press). The paper presents micrograms of total folate, where 'total folate' refers to the combination of food folate and folic acid provided by fortified foods. Paper states µg DFE = µg food folate + (1.7x µg folic acid added to or provided by fortified foods.

Additional Evidence

Dietary folate

First author and date	Study design, setting, 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
Elkin 2000	Survey 3+	Women with a viable singleton pregnancy of <20weeks gestation 3 groups Group 1: women with an uncomplicated past obstetric history who had not given birth since 1992 Group 2: women with an uncomplicated past obstetric history who had given birth since 1992 Group 3: women who had experienced recurrent	To determine knowledge of, and adherence to, current folic acid recommendations in pregnant women with uncomplicated and complicated past obstetric histories	Women completed a semi-structured interview to ascertain knowledge of recommendations and to assess their intake of folic acid including multi-vitamin preparations that contained the recommended amount of folic acid. Women were classified as taking folic acid supplements for the recommended time if they took them from before conception and during the first 12 weeks of pregnancy A 72-hour food recall questionnaire estimated the consumption of 30 folate-containing and folic acid fortified foods. 5mls venous blood were taken for folate analysis	In groups 1 and 2 those with no previous complications 56% of the pregnancies were planned in group three this was 79%. Knowledge and compliance with supplement intake recommendations was greatest in women in group 3 i.e. those with recurrent miscarriage. There was no significant differences between groups 1 and 2 More women reported being informed of the recommendations pre-conceptionally than post-conceptionally. Health professionals were most frequently cited sources of information Other sources included an advertisement by a folic acid manufacturer on London	Similar to other studies this study finds that considerably less than 50% of target group women take folic acid prior to becoming pregnant. In women with no previous complications the usage of folic acid was 26%. It is interesting to note that in this group over 40% of the pregnancies were unplanned. The women's knowledge of dietary manipulation to increase folate intake was found to be poor.

First author and date	Study design, setting, 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
		miscarriage or second trimester pregnancy losses		during routine venesection Sample size: n = 154 Group 1: 64, group 2: 43, Group 3: 47	Underground trains. Dietary knowledge was poor in all groups 28% could not name any recommended foods, 59% could name 1 or 2 and 13% could name 3 or more. No woman reported increasing her consumption of recommended foods pre-conceptionally and only one woman in group 3 increased her consumption post-conceptionally. 25% of women in group1, 28% of women in group 2 and 51% of women in group 3 took folic acid supplements for the recommended time period. Correlation between dietary folate intake per 24 hours and serum folate was insignificant for women presently taking folic acid supplements, women who had previously taken folic acid during this pregnancy and women who had never taken supplements.	

4. What interventions are effective in increasing health professional's knowledge and awareness of the recommendations for folate and folic acid in women of child bearing age who are planning a pregnancy or who might become pregnant?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic review</u> None <u>Randomised trials</u> None <u>Evaluations of UK Campaigns</u> HEA folic acid campaign 1995-1998 <u>Additional UK studies</u> Anderson 2002	The HEA campaign is a public health campaign that was evaluated using appropriate methods.	The HEA campaign was the first national multi-intervention campaign, which has been comprehensively evaluated and offers information from the UK during the mid to late 1990s. The campaign used a wide range of methods to increase knowledge amongst health professionals. These included advertising, seminars and publications. The multiple interventions used among health professionals and the diversity of the groups included mean that the impact of each individual intervention on different professional groups is unknown.

Evidence Table

Professional's knowledge

First author and date	Study design, setting, 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
The Health Education Authority Folic Acid Campaign 1995-1998. HEA, 1998	Before and after survey to assess impact of a public health interventi on 2+	The professionals surveyed were dieticians /nutritionists, family planning doctors, family planning nurses, GPs, health visitors, midwives, obstetricians/gynaec ologists 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 publications, 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 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	Doctors (GPs, family planning doctors, obstetricians and gynaecologists) had the most contact with both women planning pregnancy and pregnant women. Those respondents who said that they gave advice on a healthier lifestyle were asked about the nature of the advice they gave to women over 16 years of age. Most professionals, in particular midwives and family planning nurses, gave advice in this context on diet. In 1997only 2% (23 respondents) specifically mentioned giving advice on folic acid as part of general health advice compared with only one	These data offer an important snapshot into knowledge about folic acid among professionals working in England that had contact with women planning a pregnancy. 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

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				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.	respondent in the 1996 survey. When asked about advice to women planning a pregnancy 55% in 1996 and 71% in 1997 spontaneously mentioned folic acid. When asked about advice to pregnant women pregnancy 36% in 1996 and 39% in 1997 spontaneously mentioned folic acid. When asked specifically about dietary supplements for women planning a pregnancy 73% in 1996 and 81% in 1997 reported folic acid. In both surveys when specifically asked 73% of the professionals knew that	correct dosage or most appropriate timing for folic acid supplements. In terms of providing general health advice to women over 16 years of age folic acid was rarely mentioned. These data suggest that professionals are aware of folic acid as an issue related to pregnancy but are unlikely to spontaneously raise it with women who are not known to be planning a pregnancy.

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					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%.	

Additional Evidence

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Anderson 2002	In Depth interviews 3+	Fourteen pharmacists and fourteen medicines counter assistants were interviewed (25-40 minutes). All 14 pharmacists worked as the main pharmacist in their pharmacy. 10/14 owned a single pharmacy and one owned >1 pharmacy. One-quarter were male. A wide range of pharmacy experience and ethnic backgrounds was represented. The majority of the participants were of South Asian origin, and the population covered by the project also had a large number of South Asians. Three pharmacists and two assistants had previous experience with health	This paper reports pharmacists and medicine counter assistants experience of using the health promotion materials about folic acid.	The Health Education Authority and the National Pharmaceutical Association collaborated to produce materials for use in community pharmacies to promote consumption of an extra 400mcg/ day of folic acid by women prior to conception and during the first 12 weeks of pregnancy. Training about folic acid, prevention of neural tube defects, appropriate use of the materials, and data collection was provided to community pharmacy staff in a West London health authority. Data on sales of folic acid supplements and leaflet uptake were collected (not reported in this paper) during a 3-month campaign: Month 1 - control	Major themes were: advising regular customers compared with advising 'passing trade', and the role of pharmacists and staff from minority ethnic groups in advising customers from those groups. Pharmacists and assistants felt they would only raise the issue of folic acid if they knew the woman well, or if a woman mentioned it first. "I had to know my customers fairly well to bring up the subject of folic acid and babies." "It just depends on the patient pharmacist relationship, better to include information on the product to increase	Although pharmacists are in a position where they might have contact with women that are planning a pregnancy this study indicates that many would feel uncomfortable about raising the issue of folic acid with women that they did not know. The researchers noted that in Holland, pharmacists have been encouraged to place an extra label on oral contraceptives that states: "If you stop using the pill because of

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		promotion projects.		Month 2 - active promotional Month 3 – non-promotional	awareness, when dispensing a contraceptive or to give out a leaflet" The participants thought that raising awareness among unknown customers was probably limited to leaflets displays and posters. Most of the minority ethnic pharmacists and assistants felt they had an important role in communicating about folic acid with customers from their own ethnic groups, provided they both spoke the same language.	the wish for a child, please ask your pharmacist for information about the use of folic acid before you become pregnant". The researchers suggest this labelling could be used by pharmacists in Britain, on pregnancy tests and ovulation predictor tests as well as on oral contraceptives and information leaflets.

5. What interventions other than those about increasing intake of folate or folic acid are effective in improving nutritional status and pregnancy outcomes in non-pregnant women of child bearing age who are planning a pregnancy or might become pregnant?

Studies to be included	Evidence type	Summary of evidence quality	Comment
Systematic reviews Randomised Control Trials UK studies	<u>Systematic reviews</u> Van Teijlingen 1998 <u>Randomised trials</u> Doyle 2001 Fine 1994 (in Van Teijlingen 1998) <u>Additional UK studies</u> Doyle 1999	The evidence to answer this question comes from two randomised trials. A systematic review van Teijlingen 1998 was also identified. Inspection of their included studies revealed that only the Fine 1994 study was appropriate for answering this research question. There are flaws with both the randomised trials found.	No well designed nutrition and dietary intervention studies in non-pregnant women in developed countries that have aimed to measure pregnancy outcomes or improvements in nutrition prior to becoming pregnant were found. This is probably because there are formidable barriers to undertaking such studies. These include difficulties in identifying and recruiting target populations, difficulties in tracking populations over time, funding difficulties and difficulties in attaining statistical power when high drop out rates can be anticipated. There are also very few high quality intervention studies that aim to improve the nutrition of women that are planning to have a baby. Again this is probably because of the difficulties in undertaking such studies. These include identifying and recruiting a representative sample of women who are planning to have a baby that might benefit from a nutrition intervention.

Evidence Tables

First author and date	Study design, quality	Inclusion criteria for studies	Research question	Studies Interventions Length of follow-up, follow-up rate	Main results Effect size, CI	Comment Funding
Van Teijlingen 1998	SR 2++	Free-living women of childbearing age or pregnant women (aged 15-45 y) Healthy eating promotions[1] Health care based promotions or those based in the community 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 Searches were done of 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	What is the effectiveness of healthy eating interventions to promote healthy eating in women of childbearing age (and pregnant women)?	9 studies were included of which 5 studies were of women of childbearing age (and 4 of pregnant women). Of the former, 3 studies were RCTs, one was a non-randomised, controlled before-and-after study (CBA) (Brown 1996) and for Cox 1995 it was unclear whether the control group was randomised or not. The studies were in the USA (Cox 1995 (Virginia Expanded Food & Nutrition Education Program); Tucker 1996), Ireland (Johnson 1993), the UK (Fine 1994) and Australia (Brown 1996). 3 studies were of a younger age range (≤20-45 y) i.e. of women of childbearing age and 2 of an older range (20-66 y) (Brown; Tucker), which included some post-menopausal women. 3 studies were of lower socioeconomic groups (Johnson; Fine; Cox); 40% women in the Tucker study had a college education; and subjects were of Greek extraction in the Australian study (Brown). All 5 interventions were community-	Improvement in key nutritional outcomes in women of childbearing age <u>Knowledge</u> <u>Fine 1994 Knowledge score (Max = 36)</u> Mean scores: Before / After; Absolute between-group difference Control (n=91) 14.3 16.8 Int 1 (n=87) 14.7 20.2 +3.4 p<0.05 Int 2 (n=86) 16.6 21.3 +4.5 p<0.05 <u>Behaviour</u> <u>Johnson 1993 Percentage reporting appropriate intake</u> Before / After; Absolute between-group difference Wholefoods Control (n=105) Data not reported 24 Int (n=127) 84 +60 p<0.05 Vegetables Control (n=105) 43 Int (n=127) 81 +38 p<0.05 Fruit Control (n= 105) 28 Int (n=127) 55 +27 p<0.05	The heterogeneity of the interventions, target groups, study designs and statistical techniques meant that full meta-analysis of results was impossible so that results were presented as a narrative review. The primary outcomes for the Johnson study were child development and nutrition. The relevance of 'fat habit' in the Brown study is not understood. The report additionally reviewed reports of the US WIC Program, which did not meet the inclusion criteria,

[1] As defined by NACNE 1983

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		with relevant researchers and specialists The authors described the methodology of each study including: unit of allocation, unit of analysis, power calculation, concealment of allocation, follow–up >80%, blinded assessment of primary outcome, baseline equivalence, reliable outcome measure, protection against contamination; no overall quality scores were given		based. Study intervention details Study Type How delivered Fine Pre-defined Education Video + printed material Follow-up after 1 week Johnson Empowerment & support Regular visits by trained volunteer mothers to 1st-time mothers for 1year for 1 year Brown Pre-defined education, exercise Health & fitness group meetings weekly for 12 w + home exercise programme + written material Tucker Pre-defined exercise programme Gym-based strength training exercises 3 times /week for 12 w Cox Pre-defined education Series of community-based nutrition lessons given by 'indigenous	Energy Control (n=105) 53 Int (n=127) 94 +41 p<0.05 Brown 1996 Before After Absolute Mean±SD (n) Mean±SD (n) between group Fat habit score difference Control 4.00±1.52 (20) 3.75±2.00 (17) Int 3.15± 1.74 (26) 2.20±1.47 (25) -1.55 not sig Total cholesterol mmol/l Control 5.36±0.71 (20) 5.47±0.77 (17) Int 5.65± 1.19 (26) 5.75±0.84 (24) +0.28 not sig Triglycerides mmol/l Control 1.25±0.51 (19) 1.27±0.50 (17) Int 1.60± 1.38 (24) 1.71±2.58 (24) +0.44 not sig Body mass index Control 28.9±4.5 (22) 28.8±4.3 (21) Int 29.8± 5.5 (26) 28.1±4.8 (25) -0.7 not sig Estimated fat % Control 41.7±4.5 (22) 41.3±4.4 (21) Int 41.8± 4.1 (26) 40.7±4.4 (25) -0.6 not sig	most of which focussed on pregnancy outcomes. Funded by the Health Education Authority (HEA)

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				paraprofessionals' lessons Either 10-13 cancer prevention + nutrition lessons over 6 months or 9 nutrition lessons over 9 months	Tucker 1996 Self-reported intakes Before After Absolute Mean±SD (n) Mean±SD (n) between group Energy kcal/day difference Control 1996±402 (30) 1911±431 (30) Int 2004± 427 (30) 1779±398 (30) -132 not sig Fat % diet Control 32.1±5.7 (30) 33.1±4.7 (30) Int 34.2± 5.1 (30) 29.7±4.1 (30) -3.4 p<0.05 Carbohydrate % diet Control 53.0±6.4 (30) 52.3±4.7 (30) Int 51.4± 5.1 (30) 55.6±5.3 (30) +3.3 p<0.05 Cox 1995 Change in daily intake at end of intervention Change Absolute between-group difference Energy kcal/day Control (n=110) +171 Int 1 (n=113) +227 +56 not sig Int 2 (n=116) +103 -68 not sig Fat % energy Control (n=110) -0.03 Int 1 (n=113) -3.7 -3.4 p<0.05 Int 2 (n=116) -4.9 -4.6 p<0.05 Fibre g/day	

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					Control (n=110) +2.2 Int 1 (n=113) +3.7 +1.5 not sig Int 2 (n=116) +5.5 +3.3 p<0.05 Brief summary Fat intake - 3 studies: Tucker and Cox (2 interventions) both had significantly reduced fat consumption compared with baseline and also compared with controls, whereas for Brown 'fat habit' in the intervention group was only significantly reduced compared with baseline. Carbohydrate intake – Tucker study only: the significant increase in the intervention group compared with baseline and control group was consistent with the reported decrease in fat intake. Fibre intake – Cox study: all 3 groups reported an increase in fibre consumption which was only significant for the Int 2 group. Energy intake – 2 studies (Cox and Tucker): only the Tucker intervention showed a significant decrease in energy intake but this was just compared with baseline and was not significant when compared with the control group. Additionally Johnson reported significantly improved dietary intakes of wholefoods, vegetables, fruit and energy in the intervention group compared with controls. Brown showed significant improvements in some anthropometric measurements, total cholesterol: HDL-C ratio and fitness indicators in the intervention group	

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					but the improvements only persisted in the anthropometric measurements and fitness indicators at 12 weeks.	

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Fine 1994	RCT 1-	264 white women of lower social classes were recruited in Leeds following a questionnaire survey The study was conducted between April 1989 and December 1990	To determine if basic nutrition can be taught successfully to women with no previous specialist knowledge and to evaluate teaching materials that take into consideration an individuals ability and motivation No power calculation is reported	Using pre-determined criteria the women were assigned to four groups: low motivation low ability LMLA; high motivation and low ability HMLA; low motivation and high ability LMHA; high motivation and high ability HMHA. In each category the women were randomly allocated to a baseline group, a control group and an intervention group. The baseline group were included to assess the impact of publicly available information. The baseline group received no information and did not see a video. This group is the true control population Two videos were produced a test video and a control group video. Both videos were about nutrition but the test video contained additional motivational material. Women in the control group and in the test group were interviewed about their nutritional knowledge before seeing the video and then again one week later. Mean scores for nutrition knowledge were calculated for each	The primary outcome was a change in the mean score about nutritional knowledge across the three groups. <u>Baseline group (no intervention a true control group)</u> Mean scores n Before After LMLA 27 10.2 12.8 LMHA 22 14.9 17.2 HMLA 14 12.6 14.7 HMHA 28 18.7 21.2 <u>Control group (nutrition only video)</u> Mean scores n Before After LMLA 28 12.4 17.9 LMHA 20 14.6 20.7 HMLA 16 13.6 18.9 HMHA 23 18.5 23.6 <u>Test group (nutrition and motivation video</u> Mean scores n Before After LMLA 18 12.9 17.1	There are several problems with the design of this study which have been reported in systematic review (van Teijlingen, HEA 1998). The lack of a power calculation and the complexity of the study design suggest that caution is needed when interpreting the results.

				group.	LMHA 20 17.4 21.5 HMLA 16 15.8 21.9 HMHA 23 19.0 23.3 The control group and the test group scored significantly higher ($p<0.001$) at the second questionnaire interview than the baseline group. The motivational component of the test groups video did not increase scores significantly more than the control group. Women's nutritional knowledge can be increased using videos irrespective of their motivation	

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Doyle 2001	RCT 1-	Healthy English-speaking mothers with live low-birth weight (≤2.5 kg) babies, intending to have further pregnancies, living in deprived inner city area of London, without chronic illnesses, not already taking supplements. 224 women delivered low birth baby and were potentially eligible.	To evaluate if micronutrient supplementation improved the nutritional status of women with poor diets during the inter-pregnancy interval for women with low-birth weight babies Power calculation not reported	All participants received written dietary advice based on analysis of their diet diaries and general lifestyle advice on preparing for pregnancy. All were invited to keep a second 7-day diet diary at 9 months – completed with nutritionist Intervention (I): given daily multivitamin-mineral supplement and docasahexaenoic supplement (single cell oil) 150 mg/day. Intervention was given between 3-9 months after delivery Control (C): Not given supplements Serum and erythrocyte folate, serum ferritin and haemoglobin at 3 and 9 months compared between groups	Of the 224 eligible women 100 were excluded because they had left hospital, did not speak English, were taking supplements or for medical reasons. Of the remaining 124 eligible women 33 refused to take part. Of the 91 that agreed 36 failed to complete a diary Of the 55 that completed a diary a further 17 failed to complete the study. Only 38 women completed the study. 11 had adequate diet and did not receive supplements. 27 women had inadequate diet of which 11 were given supplements and 16 were not. Impact of supplements in 27 women categorised as having inadequate diet Serum folate (nmol/l) mean 3m 9m I 6.74 12.5 C 5.64 5.57 (p<0.001) Erythrocyte folate (nmol/l) mean 3m 9m I 227 346	Of the 224 women eligible to participate only 38 mothers completed the study. This illustrates a difficulty of undertaking research in deprived inner city populations. This high drop out rate and small number completing the study also compromises the study and means that the findings of the study need to be treated with caution.

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					C 226 255 (p<0.001) Serum ferritin (µg/l) mean 3m 9m I 25.5 36.0 C 25.7 25.4 (p<0.01) Haemoglobin (g/l) mean 3m 9m I 128 126 C 127 131 (p not significant)	

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Doyle 1999	Before and after study 2-	Inner city population in London Mothers who had a baby weighing ≤2.5kg born at the Homerton Hospital Mothers interviewed. Those reporting that they might have another baby were included. 111 mothers agreed to participate, 77 completed the 7-day diaries.	To evaluate the effectiveness of nutrition counselling during the inter-pregnancy interval	Participants providing consent completed a 7-day diet diary to estimate their usual nutrient intake When the diet had been assessed the results were discussed with the mother who was then seen regularly by a dietician and co-workers from appropriate ethnic backgrounds at a drop-in Mother and Baby Clinic. The mothers were seen from 4 – 6 weekly intervals depending on how soon they intended to have another baby. They were also encouraged to drop-in without an appointment. Monthly group events for all mothers and children took place which included budget cookery demonstrations when mothers and children were encouraged to taste unfamiliar nutrient rich foods. Other	Of the 77 women recording baseline food diaries the diets of 70 (91%) were defined as inadequate. These 70 women received the intervention. Of these 41(59%) of the mothers recorded a second diary after 6 months exposure to nutrition counselling. Mother's views 26% were unsure or did not think there was a relationship between food and health, 21% were unsure or did not believe what they ate would affect the health of their baby, 34% were not or only slightly interested in nutrition, and 39% never read food labels. 83% said the likes and dislikes of their partner or their family were more important than their own when planning meals Post intervention intakes Although there were significant increases in the intake of protein ($p = 0.019$), zinc ($p = 0.038$), niacin equivalents ($p = 0.007$) and vitamin B_6 ($p = 0.026$) there was only a small increase in the proportion of	This was a feasibility study with a small proportion completing follow-up therefore any conclusions drawn from this study must be tentative.

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				events included talks on nutrition for the whole family and a visit to a supermarket to discuss choosing healthy alternatives. During the 6-month period 2 newsletters were produced to maintain awareness of the aims of the project. At the end of the 6-month intervention period mothers were again asked to keep a 7-day diet diary so that changes in dietary intake could be assessed.	mothers who met recommended dietary reference values Percentage of 41 women that met the Dietary Reference Values before and after the intervention Before After Energy 15% 29% Protein 73% 76% Fibre 12% 5% Calcium 46% 56% Folate 22% 29% Vitamin C 80% 63%	