# The effectiveness of public health interventions to improve the vitamin D status of pre-conceptual, pregnant and postpartum women and children in low income households

#### **Evidence tables**

#### Stand alone vitamin D supplementation

Authors Year Country Study Design Quality	Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Brooke et al. 1980) London (51.5° N), UK RCT Evidence level: 1+ Associated references (Brooke 1981, Maxwell 1981)	Asian pregnant women (Indian, Pakistan, Bangladesh, Sri Lanka, Mauritius an east Africa) living in Tooting, south London (51.5° N) No significant differences between the two groups in age, parity, height, vegetarian status, country of origin, serum 25 OHD levels (range from undetectable to 92 nmol/l; 71% of vegetarians and 12% of non- vegetarians had undetectable levels, p<0.01) 126 Asian women Calciferol group: 59 Placebo group: 67 Randomisation by hospital pharmacy	Study Question: What are the effects of vitamin D on maternal and infant calcium homeostasis and fetal growth? Statistical Analysis: Comparative analysis between a treatment group and a placebo group	Vitamin D supplements (calciferol 1000 IU/day[25 ug/day]) given during the third trimester vs. placebo	Intention-to-treat analysis performed Mothers: Mean plasma 25 OHD concentration (nmol/l) Calciferol group:168 ± 96.0 Placebo group: 16.2 ± 22.1 (WMD 151.80, 95% Cl 126.74 to 176.86) Results 'pooled' from samples taken in summer months and winter months separately, no significant difference between the two lots of samples, though mean levels were higher in summer months in mothers at 28 weeks, at term and also in cord blood Significant correlation in 25 OHD levels between maternal and cord blood (r=0.93, p<0.01) Mean daily weight gain (g):	Though likely to be applicable to pregnant Asian women in regions of similar latitude and sunlight hours. This is the only RCT assessing the effect of vit D in Asian women	This RCT was conducted in 1977 during autumn- winter, throughout 1978 and Spring-summer 1979 Allowance made for seasonal variation No allocation details

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	women's hospital number			Calciferol group: 63.3 ± 20.70 Placebo group: 46.4 ± 29.50 (WMD 16.9, 95% Cl 8.08 to 25.72)		
				Infants: Mean birth weight (g) Calciferol group: 3157 ± 468.5 Placebo group: 3034 ± 523.9 (WMD 123.0, 95% CI -50.29 to 296.39)		
				No harmful/adverse effects documented No long-term follow-up data		

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& Wood 1981) London (51.5° N), UK RCT Evidence level:	Asian infants 0 to 12 months, born to mothers (living in London) who received antenatal vit D supp or no antenatal vit D supp 117 infants	Study Question: What are the effects of antenatal vit D supp on infant weight at 1 year? Statistical Analysis: Comparative analysis between a treatment group and a placebo group	Antenatal vit D supp to mothers during pregnancy vs. no antenatal vit D supp to mothers during pregnancy	Infant weight Birth: Antenatal vit D: $3.13 \pm 0.49$ Kg Control: $3.05 \pm 0.51$ kg (WMD 0.08kg; 95% CI -0.06 to 0.22) At 3 months: Antenatal vit D: $5.65 \pm 0.58$ Kg Control: $5.40 \pm 0.54$ kg (WMD 0.25kg; 95% CI 0.05 to 0.45) At 6 months: Antenatal vit D: $7.56 \pm 0.60$ Kg Control: $7.09 \pm 0.59$ kg (WMD 0.47 kg; 95% CI 0.25 to 0.69) At 9 months: Antenatal vit D: $8.54 \pm 0.59$ Kg Control: $8.29 \pm 0.57$ kg (WMD 0.25kg; 95% CI 0.04 to 0.46) At 12 months: Antenatal vit D: $9.39 \pm 0.66$ Kg Control: $8.98 \pm 0.62$ kg (WMD 0.41 kg; 95% CI 0.18 to 0.64) Increments over 0-12 months: Antenatal vit D: $6.39 \pm 10.53$	Though likely to be applicable to pregnant Asian infants in the UK, this is the only RCT assessing the effect of antenatal vit D in Asian infants, and was conducted in 1980.	Postnatal vit D supplements were not routinely given. Mean length of breastfeeding 3.2 months in supplemented group vs. 3.5 months in the control group (NS). It is possible that the treated group may have been given better postnatal nutrition than the control group.

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				0.78kg Control: 5.92 ± 0.92 kg (WMD 0.47kg, 95% CI 0.16 to 0.78).		

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(Stephens et al. 1981) Rochdale (53.6° N), UK RCT Evidence level: 1-	women Oral vit D (n=12) IM vit D (n=12)	Study Question: What are the effects of a single dose of ergocalciferol orally or intramuscularly during the autumn on serum 25 OHD? Statistical Analysis: comparison analysis of the two treatment groups	A single dose of oral ergocalciferol 2.5 mg (100,000 IU) vs. a single dose of intramuscular calciferol given in the Spring for 5 months	Serum 25 OHD before and after vit D treatment (nmol/l) Pre-treatment (Spring 1980) Oral vit D: $8.3 \pm 2.8$ IM vit D: $7.3 \pm 3.5$ (NS) Pre-treatment (Autumn 1980) Oral vit D: $16.5 \pm 8.5$ IM vit D: $14.0 \pm 7.3$ (NS) At 1 month: Oral vit D: $52.5 \pm 12.0$ IM vit D: $52.5 \pm 12.0$ IM vit D: $52.5 \pm 13.8$ (WMD 20.0, $95\%$ CI 9.65 to $30.35$ ) At 3 months: Oral vit D: $29.5 \pm 7.0$ IM vit D: $29.5 \pm 7.0$ IM vit D: $29.5 \pm 7.0$ IM vit D: $24.5 \pm 5.3$ IM vit D: $23.5 \pm 11.6$ (NS) At 5 months (Spring 1981): Oral vit D: $24.5 \pm 5.3$ IM vit D: $23.5 \pm 11.6$ (NS) Pre-treatment vs. 5 months after treatment Oral: WMD 8.00, 95% CI 2.33 to 13.67 IM: WMD 9.50, 95% CI 1.75 to 17.25 The range produced by oral vitamin D was much less than the range produced by IM vitamin D (mean 24.5,		This study was conducted in 1981. Method of randomisation and allocation concealment not reported Small sample size No intention-to-treat analysis

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				range 19.3 –34.3 nmol vs. mean 23.5, range 12.8–52.3). At one year after the study, serum 25 OHD concentrations, every patients had a level above 12.5 nmol/I No adverse effects documented		

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(Cockburn, Belton, & Purvis 1980) Edinburgh (55.6° N), UK Non-RCT Evidence level: 2+	Pregnant women living in Edinburgh Both groups comparable for social class, parity and age (no information on ethnicity status) No information on whether 25 OHD levels were similar in the 2 groups 1139 women and their infants Vit D supp (n=506) Placebo (n=633)	supplementation during pregnancy beneficial to mothers and their infants? Statistical Analysis: Comparative analysis between a	Daily vitamin D 400 IU (10ug) from 12th week of pregnancy (given during the months of September to May) till delivery vs. placebo	Maternal plasma 25 OHD (nmol/l; values cubed of mean cube root) At 24 weeks: Vit D group: 39 (n=82) Placebo group; 32.5 (n=82) (p<0.01) At 34 weeks: Vit D group: 44.5 (n=80) Placebo group; 38.5(n=80) (p<0.05) At delivery: Vit D group: 42.8 (n=80) Placebo group; 32.5 (n=84) (p<0.001) Infant plasma 25 OHD (nmol/l; values cubed of mean cube root) At day 6 Vit D group: 34.5 (n=54) Placebo group; 20.3 (n=86) (p<0.001) At day 6 Vit D group: Breast fed: 25.2 (n=12) Artificial milk fed: 34.4 (n=41) (p<0.01) Placebo group: Breast fed: 15.4 (n=57) (p<0.01) Estimated dietary	Maybe applicable to UK populations and setting depending on latitude of regions	This study was conducted in 1980. A non-RCT - subject to sampling bias and confounders (e.g., ethnicity status of the groups was not reported, self-report of dietary vit D intake, compliance)

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Quality				vitamin D intake based on recall at 34 weeks (n=84): 91 IU (2.3 ug) /day Significant correlation between maternal and infant plasma 25 OHD (r=0.71) In both groups, values of plasma 25 OHD 'peaked' during July and August No adverse effects documented		

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Pietrek et al. 1976) Glasgow (55.9° N), UK Non-RCT Evidence level: 2-	Asian families living in Glasgow 66 members (20 adults and 46 children) of 14 Asian family in 3 groups Group 1: 16 members (4 families) Group 2: 18 members (4 families) Group 3: 32 members (6 families) No sig difference in baseline serum 25 OHD concentration between the 3 groups	Study Question: What are the effects of vitamin D fortified chupatty flour and weekly vitamin D in reducing the incidence of rickets and osteomalacia in the Asian community? Statistical Analysis: Comparative analysis between treatment groups and the control group	Group 1: no vit D supp, no vit D fortified chupatty flour (control) vs. Group 2: weekly vit D supp 3000 units (administered by health visitor to 3 families, I family self-administered) vs. Group 3: vit D fortified chupatty flour (6000 units /kg flour) for 6 months	Serum 25 OHD concentrations: At baseline (Dec) Group 1 (control): 4.7 $\pm$ 0.5 ng/ml Group 2 (weekly vit D Supp): 6.8 $\pm$ 1.1 ng/ml Group 3 (vit D fortified flour): 4.0 $\pm$ 0.5 ng/ml (Group 2 vs. group 1: WMD 2.10, 95% CI 1.54 to 2.66)(Group 3 vs. group 1: WMD -0.70, 95% CI -1.00 to -0.40) At 3 months (March) Group 1 (control): 3.8 $\pm$ 0.5 ng/ml Group 2 (weekly vit D supp): 15.5 $\pm$ 2.3 ng/ml Group 3 (vit D fortified flour): 18.0 $\pm$ 1.2 ng/ml (Group 2 vs. group 1: WMD 11.70, 95% CI 10.61 to 12.79)(Group 3 vs. group 1: WMD 14.20, 95% CI 13.72 to 14.68) At 6 months (June) Group 2 (weekly vit D supp): 18.1 $\pm$ 2.9 ng/ml Group 2 (weekly vit D supp): 18.1 $\pm$ 2.9 ng/ml Group 3 (vit D fortified flour): 19.5 $\pm$ 1.2 ng/ml Group 3 (vit D fortified flour): 19.5 $\pm$ 1.2 ng/ml Group 2 (weekly vit D supp): 18.1 $\pm$ 2.9 ng/ml Group 3 (vit D fortified flour): 19.5 $\pm$ 1.2 ng/ml	Likely to be applicable in regions of similar latitude in the UK. However, in 1978, the Working Party at COMA concluded that mandatory fortification of any flour, milk or butter with vitamin D was not a practical solution	A non-RCT conducted in 1973 Small sample size Confounders: sampling bias unequal serum 25 OHD concentrations between the 3 groups at baseline attrition compliance

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				14.97) Biochemical abnormalities suggestive of rickets: At 6 months Group 1: 2 members Group 2: 1 member Group 3: 0 2 individuals were followed up for 2 years, the serum 25 OHD levels had fallen to pre- study levels (data not available) No adverse events documented		

Authors Year Country	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations	Confounders & Comments
Study Design Quality					and settings	
	Asian mothers and babies living in Leeds 76 babies Group 1: Asian babies born to women who received no vit D	Study Question: What are the effects of vit D deficiency on biochemical measurements and skeletal mineralisation of the fetus?	Antenatal vit D supplementation given during the 3rd trimester vs. no antenatal vit D supp in Asian mothers vs. white mothers with normal vit D conc	Cord blood 25 OHD concentrations (nmol/l) Group 1: 5.90 ± 0.94 Group 2:15.20 ± 3.15 Group 3: 33.40 ± 3.60 (p<0.001) (Group 1 vs. Group 2 - NS)	Likely to be applicable to UK populations and settings, depending on regional latitudes an sunlight hours.	The study was conducted in 1983 Possible confounders: no maternal serum 25 OHD levels sampling bias seasonal variation non-compliance
Evidence level: 2–	supp (n=45) Group 2: Asian babies born to Asian women who received vit D supp in the 3rd trimester (n=19) group 3: Asian babies born to white women (n=12) There was no significant difference between the 3 groups of babies in maternal age, gestational age, ratio of boys to girls, or the proportion of craniotabes	Statistical Analysis: Comparative		% of 25 OHD concentrations below 10nmol/I: Group 1: 91% Group 2: 58% Group 3: 0% Bone mineral content (by scanning, arbitrary units proportional to mineral mass per unit length of the radius and ulna combined) within 5 days after birth Group 1: $3.10 \pm 0.10$ Group 2: $3.19 \pm 3.15$ Group 3: $2.94 \pm 0.19$ (NS) No sig association between bone mineral content and cord blood 25 OHD levels No report of adverse events with		accuracy of BMC scanning

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	Asian women living in Wales (African, Afro- Caribbean, Asian, Far Eastern, Middle-Eastern) in the 3rd trimester of pregnancy 160 women	Study Question: Is prenatal vitamin D supplementation effective in treating vit D deficiency in Asian women? Statistical Analysis: Before and after treatment comparison	Vit D supplement 800 IU/day or 1600 IU/day depending on serum 25 OHD levels at first antenatal clinic A vit D level of < 8ng/mL(<20 nmol/l) taken as the cutoff value for commencing calciferol 800 IU/day	80/120 (50%) women had vit D levels < 8ng/ml and were given vit D supplementation Subnormal vit D levels found in: 50% of women who had been in the UK for > 3 years 25% of women who have lived in the UK for 3 years 25% of women who were born in the UK Maternal serum 25 OHD concentrations (ug/mL): At booking (n= 58): 5.79 ± 0.91 Post-delivery (n=58): 11.24 ± 6.34 Vitamin D not affected by religion fluency in English or dressing habit	Likely to be applicable in the UK populations and settings	Possible seasonal variation in sunlight exposure but vitamin D status.

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(Mallet et al. 1986) Rouen (49.4° N), France RCT Evidence level: 1+	White pregnant women living in Rouen 77 women Vit D supp 1000 IU/day (n=21) Single dose of 5mg (n=27) control (n=29) No significant difference between the 3 groups in age, parity, frequency of outings, calcium intake	Study Question: What are the effects of daily vitamin D supp compared with one single dose of vit D or no vit D on serum 25 OHD in pregnant women? Statistical Analysis: Comparative analysis between treatment group and placebo group	Vit D supp 1000 IU/day (25 Ug/day) given during the third trimester vs. Single dose of vit D 5mg (200,000 IU) given at 7th month vs. No vit D supp	Women at delivery Mean serum 25 OHD levels Daily vit D: 25.3 $\pm$ 7.7nmol/l Control: 9.4 $\pm$ 4.9 nmol/l (WMD 15.90, 95% CI 12.15 to 19.65) Single does vit D: 26.0 $\pm$ 6.4 nmol/l Control: 9.4 $\pm$ 4.9 nmol/l (WMD 16.60, 95% CI 13.60 to 19.60) Infants (born in February-March): Mean birth weight Daily vit D:3370 $\pm$ 376g Control: 3460 $\pm$ 377g (WMD –90.00g, 95% CI –298.48 to 118.48) Single doe of vit D: 3210 $\pm$ 468g Control:3460 $\pm$ 377g ((WMD –250.00g, 95% CI –492.68 to –732) No report of adverse events	May not be applicable to Caucasian women living in UK which has a different latitude than the study region (NW France), also different food fortification policy of the 2 countries	This RCT was conducted in winter (Feb -March) 1986 Small sample size Randomisation generated by using a table of random numbers - no further details Method of allocation concealment not reported Dairy products not fortified in France. No power calculation.

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(Delvin et al. 1986) Lyon (45.7° N), France RCT Evidence level: 1+	Pregnant women (ethnicity unknown) in the 3rd trimester 40 women Data available for: Vit D group (n=20) no vit D group (n=20) All selections in December and all deliveries in June Both groups comparable in maternal and gestational age, parity and infant birth weight (no data given) Biochemical parameters similar in both groups of women before initiation All infants singletons, breast- fed from 6th hour after birth	status during the last trimester of pregnancy on	Vit D supplementation 1000 IU/day (25 ug/day) initiated at the 3rd trimester vs. no vit D supplementation Compliance verified by weekly visit by a midwife	Serum 25 OHD concentrations (ng/ml) Maternal at delivery (June) Vit D: 26 $\pm$ 7SD (n=40) Control: 13 $\pm$ 8 SD (n=40) (WMD 13.70, 95% CI 10.41 to 16.99) (unclear if SD or SEM used Cord blood Vit D: 18 $\pm$ 2 sem (n=14 pairs) Control: 7 $\pm$ 1 sem (n=13 pairs) (WMD 11.0, 95% CI 6.78 to 15.22) Infants (at day 4): Vit D: 13 $\pm$ 1 sem (n=14 pairs) Control: 5 $\pm$ 1 sem (n=14 pairs) Control: 5 $\pm$ 1 sem (n=12 pairs) (WMD 8.0, 95% CI5.23 to 10.77) Significant correlation between maternal and venous cord blood calcium and 25 OHD in both groups (0<0.005)	Unlikely to be applicable to UK populations: milk and dairy products enriched with vit D in UK, also latitudinal variation in sunlight availability	Neither milk nor dairy products are enriched with vit D in France Drop outs: Vit D group: 5 Control group: 1 Degree of exposure to sunlight and ethnicity of mothers not known

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(Ala-Houhala 1985) Tempere, Finland (61° N) RCT Evidence level: 1-	Breastfeeding mother-infant pairs Healthy term infants 92 mother-infant pairs (breast-fed) Studied in winter (n=47) Studied in summer (n=45) Group 1 Maternal vit D (1000 IU/day [25 Ug/day]after delivery)/no infant vit D (n=17 in winter, n=15 in summer) Group 2 No maternal vit D/infant vit D 400 IU/day (n=15 in winter, n=16 in summer) Group 3 No maternal vit D/infant vit D 1000iu/day (n=15 in winter, n=14 in summer) Half of mothers received no vit D supp during pregnancy One-fourth received vit D supp 500 IU/day during middle	Study Question: What are the effects of vit D supp (with or without in mothers and infants) on serum 25 OHD levels during winter and summer? Statistical Analysis: Comparative analysis between treatment groups	Maternal vit D/no infant vit D vs. No maternal vit D/infant vit D 400 vs. No maternal vit D/infant vit D 1000	Serum 25 OHD concentrations Maternal data (absolute data presented graphically) At delivery Sig higher 25 OHD in summer than in winter in all 3 groups of mothers (p<0.001 in groups 1 and 2; p<0.01 in group3) At 8 weeks (in winter) Sig higher in group 1 than in group 2 and 3 (p< 0.001) In summer No sig diff between group 1 and 3 In winter groups (n=47) 12/47(26%) of groups 1, 2 and 3 at delivery or at 8 weeks had levels < 5ng/ml and 16/36(44%) of groups 2 and 3 at 8 weeks had levels < 5ng/ml but not at 20 weeks after delivery when it was spring No signs of clinical or biochemical rickets seen in the infants with 25 OHD levels In summer group (n=45) Groups 2 and 3 No women of groups 1,	May not be applicable to UK population due to different regional latitudes, amount of sunlight and food fortification policy	Study conducted in 1985 Different maternal vit D supp during pregnancy Small sample size. No power calculation. Applicability uncertain.

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	pregnancy One-fourth received vit D 500 IU/day during entire pregnancy 25 OHD levels comparable in all infants at beginning of study			2 and 3 at delivery had levels < 5ng/ml at delivery or at 8 weeks 2/29(7%) of groups 2 and 3 had levels < 5ng/ml at 20 weeks when winter beginning (December) Infant data (absolute data presented graphically) 25 OHD levels sig higher in all summer groups than in all winter groups (p<0.001) In winter no sig diff in levels between the 3 groups in winter (at delivery) In summer, sig lower levels in group 3 than in group 1 (p<0.05) In winter At 8 weeks: levels sig lower in group 1 than group 2 and group 3 (p<0.001) 10/18(56%) in group 1 had levels below risk limit for rickets At 20 weeks (Spring) 2/17 (12%) of group 1 had levels below risk limit for rickets In summer		
				No sig diff in levels		

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				between group 1 and group 2 Levels sig lower in group 1 than in group 3 (p<0.001) 1 infants in group 1 had levels below risk limit for rickets at 20 weeks when it was December No signs of clinical or biochemical rickets seen in the infant with 25 OHD levels below risk limit for rickets No adverse events documented		

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(Hollis & Wagner 2004) South Carolina (32.8° N), USA RCT Evidence level: 1-	Fully lactating women within 1 month after birth and who planned to continue full breast feeding for the next 3 months 18 breast-feeding women and their infants The 2 groups were similar in age, ethnicity profile, insurance status, parity, pregnancy interval, sex of infants, birth weight or gestational age and no difference in baseline vit D indices for mothers and infants Exclusion criteria: preexisting type 1 diabetes, hypertension, parathyroid disease	Study Question: What are the effects of vit D supp of 1600 IU/day vs. 3600 IU/day in preventing hypovitaminosis D for mother and nursing infants? Statistical Analysis: Comparative analysis between 2 treatment groups with each subject acting as her own control	Group 1 (n=9) received vit D2 1600 + D3 400 IU/day (2000 IU) vs. Group 2 (n=9) received vit D2 3600 + D3 400 IU/day (4000 IU) (Both groups also received additional multivitamin capsules containing vit D3 400 IU /day) Subjects served as own control	Total circulating serum 25 OHD concentrations (ng/mL)		Insufficient information provided – difficulty grading study. A study of vitamin D dose finding, conducted in the US Women acting as own control ie no placebo group. Small sample size

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				Group 1 vs. Group 2 At 3 months: WMD 3.00, 95% CI–1.14 to 7.14)		
				No adverse events documented		

Authors Year Country Study Design Quality		Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Greer & Marshall 1989) Massachusetts (42.4° N), USA RCT Evidence level: 1+	White infants born at term and exclusively breast-fed for 6 months (Mothers received supplemental vit D during pregnancy -dose unknown) 58 infants Vit D sup (n=22) Group 1 Placebo (n=24) Group 2 Control group (n=12) Group 3 13 infants born in summer 33 infants born in summer 33 infants born in winter Additional 12 full- term healthy and exclusively formula-fed infants used as a comparison group (no randomisation process) No difference between the groups in sex, gestational age, birth weight and serum 25 OHD levels at start of study. Free from major congenital abnormalities, neurologic	What are the effects of vit D supp in breast-fed white infants on bone	Vit D supplements 400 IU/day (10 ug/day) within the first week of birth vs. daily placebo (vs. a convenience sample of formula-fed infants) Vit D free formula given to mothers for emergency situations	Total serum 25 OHD concentrations (ng/ml) At 6 weeks Group 1: $30.25\pm 9.54$ Group 2: $15.76\pm 9.81$ Group 3: $30.21\pm 6.08$ At 3 months Group 1: $38.89\pm 10.34$ Group 2: $15.72\pm 11.25$ Group 3: $37.24\pm 6.08$ At 6 months Group 1: $39.96\pm 11.86$ Group 2: $23.53\pm 9.94$ Group 3: $37.57\pm 8.54$ Winter-born infants vs. summer-born infants vs. summer-born infants At 6 months Group 1: Winter-born: $36.7\pm$ 12.9 (n=12) Summer-born: $37.4\pm 10.9$ (n=7) (NS) Group 2: Winter-born: $25.1\pm$ 10.2 (n=13) Summer-born: $20.2\pm$ 9.3 (n=6)(NS) Group 2 winter-born infants $13\pm 7.1$ at 6 weeks vs. $25.1\pm 10.2$ (p<0.01) Summer-born infants No sig changes in Group 1 and 2 between 6 weeks and 6 months	May not be applicable to UK population due to difference in regional latitudes: Britain (50-61° north) Massachusetts (42° north)	83% infants completed the study There were more babies born in winter (33) than in summer (13) Small no of babies were given vit D-free formula during the study. Two fathers of infants were non-Caucasian

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	disorders or gastrointestinal disease			Bone mineral content (measured by photon absorptiometry of the distal radius)(mg/cm) All 3 groups had an increase in BMC during the study		
				At 6 months Group 1: 89.5±12.5 Group 2: 101.0±17.9 (p<0.05)		
				Group 2: $101.0\pm17.9$ Group 3: $107.4\pm10.6$ (p<0.02) (Change in BMC for group 3 sig higher than the combined change in BMC for both groups 1 and 2 [p<0.02)		
				Mean body weight (g) Group 1:7570 ± 858 Group 2: 7752 ± 1182 Group 3: 7633 ± 1002 (NS)		
				Maternal mean vit D intake (IU/day) of groups 1 and 2: 701±242 at 6 weeks 652±181 at 6 months		
				Mean weekly UVB exposure: no sig diff between the 3 groups		
				No adverse events documented		

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(Greer, Searcy & Levin 1981) Ohio (40.1°N), USA RCT Evidence level 1+ Associated reference (Greer 1982)	Breast-fed infants born at term, healthy and of appropriate gestational age (38-40 weeks) 18 infants vit D supp (n=9) placebo (n=9) Additional comparison with a formula-fed control group (n=12) No sig difference in their gestational age, birth weight or sunlight exposure between the 2 groups 16 infants born in summer (2 in November) 17 Caucasian (1 Asian-Indian) For bone mineral content: Additional control group: term, healthy, exclusively formula-fed infants	treatment and control groups	Vit D supp 400 IU/day vs. placebo (vs. a convenience sample of formula-fed infants) Compliance estimated by regular enquiries of intake, record of refills, maintained by physicians who dispensed the supp and the placebo		May not be applicable to UK populations and settings due to difference in regional latitude and food fortification policy	published in 1982 Double blind (mothers and investigators) RCT small sample size data details reported graphically accuracy of BMC scanning

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(Greer et al. 1982)	born at term, healthy and of appropriate gestational age (38-40 weeks)	Study Question: What are the effects of supplemental vit D on bone mineralisation and serum 25 OHD levels? A follow-up	Vit D supp 400 IU/day vs. placebo	At 26 weeks	May not be applicable to UK populations and settings (latitude variation) and food fortification policy	Published in 1982 small sample size data details reported graphically
RCT Evidence level: 1+	vit D supp (n=6) placebo (n=7) No sig difference in their gestational	study at 1 year Statistical Analysis: Comparative analysis between		concentrations (ng/ml) At 26 weeks Vit D supp: 32.7 placebo: 12.9 At 52 weeks		
Associated reference (Greer 1981)	age, birth weight or sunlight exposure between the 2 groups At 6 months, the study was unblinded to the mothers of the infants and all infants were allowed solid foods and the placebo group was given daily vitamin D supplement of 400 IU	treatment and control groups		Vit D supp vs. placebo (NS) None of the infants had clinical signs of rickets No adverse events documented		

Study Design Quality	Idy Research Iation Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
N), Scotland aged 19- (median Uncontrolled before and after study Evidence level: 2- Blood sa the pre-c survey of osteoma taken fro women ( aged 19- (median Target pr Asian Glasgow (estimate families, populatio 16,000 [s Dunnigan Blood sa the pre-c survey of osteoma taken fro women ( aged 19- (median Slasgow (estimate families, populatio 16,000 [s Dunnigan taken fro women ( aged 19- years) se randomly general p	h and usehold, 60 yearsWhat are the effects of health education to Asia women on prevention of vitamin D deficier supported by provision of vitam D supplements at cost price?ad 3000Statistical Analys Before and after campaign outcomesann 14- see n 1985])Statistical Analys Before and after campaign outcomesacia was m n=203; to 60 elected rom 3 oractices; ipaign mples of m group, g 80 -47 om 3thH	<ul> <li>osteomalacia.</li> <li>Components of intervention</li> <li>1. Health education to promote vit D self-</li> <li>n supplementation</li> <li>2. Provision of vit D supp (10 ug tablets) at cost price (£2.56 per annum at 1984</li> </ul>	<ul> <li>A. No of home visits: 1883 (924 to Sikh families, 959 to Muslim families)</li> <li>B. No. of visits to clinics:184</li> <li>C. No of visits to temples:35</li> <li>D. Attitudes of Asian women to supplement purchase and self- supplementation</li> <li>1-3 months after campaign (n=252)</li> <li>D1. Currently taking vit D supp: 59%</li> <li>D2. Taking one 10-ug tablet daily: 68%</li> <li>D3. Reasons for taking vit D supp: 'prevention of rheumatic aches and pains, 'to give energy', 'to improve digestion'</li> <li>7-10 months after campaign (n=188)(home sale of supp already withdrawn):</li> <li>D4. Heard about Asian osteomalacia: 93%</li> <li>D5. Purchased vit D supp: 71%</li> <li>D6. Not interested in further purchases: 5%</li> <li>D7. Currently taking vit D supp: 19%</li> <li>D8. No attempt made to purchase further</li> </ul>	Likely to be applicable to UK populations and settings if properly adapted	This campaign for Asian women was an extension of the Glasgow rickets campaign for children (1979-1983). The age ranged from 19 to 60 years, can be construed to include women who are pregnant, postnatal, breastfeeding or planning a pregnancy. Possible confounders: No control group Sampling bias No report of response rates from Asian women Age Place of birth (country of origin) Dress habit Time spent out of door (sunlight exposure) Seasonal variation Dietary habit Extent of prior knowledge Spontaneous recovery Lack of objective measurement that vit D supp was consumed as advised

#### Evidence tables: Interventions to promote uptake of vitamin D supplements

Authors Year Country Study Design	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
Quality			<ul> <li>4. Explanatory leaflets (in English, Guajarati, Hindi, Urdu and Punjabi) on: the symptoms of osteomalacia prevention of osteomalacia need for supplementation, preparations available in clinics costs of proprietary vit D preparation and clinics opening times.</li> <li>5. More detailed explanatory leaflets and progress letter prepared for Health professionals concerned with the campaign (Clinic staff and general practitioners)</li> <li>Execution of campaign</li> <li>6. Link workers visited Asian families at home, antenatal clinics and Health centres attended by Asian women and sold vit D supp for self- administration.</li> <li>7. They also visited Sikh and Hindu temples to explain the purpose of the campaign in Hindi or Punjabi</li> <li>8. Regular liaison visits by campaign co-ordinators and health education officers to clinics to monitor supplement uptake</li> </ul>	D9. Reasons for not purchasing vit D supp: 'not interested', 'feel no different', 'weight gain' E. Attitudes of health professionals to the campaign (n=500) At 2 years E1: Response rate: 38% E2. Heard of campaign: 74% E3. Heard of ts extension to Asian women: 36% E4. Received literature about campaigns: 25% E5. Indicated desire for more information: 27% E6. Prescribed vit D supp for Asian children: 11% E7. Prescribed vit D supp for Asian women: 3% E8. Asked for vit D supp for Asian women: 6% (No comparative information obtained from Health Visitors concerning the campaign because the nursing management discouraged the distribution of a questionnaire) F. Mean serum 25 OHD (nmol/l) Precampaign (n=203): 26 (95% CI 7.5 to 80.0)		

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
				Post-campaign (n=139): 23 (95% Cl 8.0 to 63.0)(p<0.05)		
				Paired sample (n=59) Precampaign: 28 (95% CI 10.0 to 79.0) Post-campaign:21 (95% CI 8.0 to 55.0)(p<0.003)		
				'Present' vit D takers (n=29): 29 (95% Cl 10 to 83) 'Past' vit D takers (n=74): 21 (95% Cl 8.0 to 55.0) 'Never' vit D takers (n=33): 20 (95% Cl 8.0 to 52.0)		
				G. Prevalence of osteomalacia (indicated by 25-OHD < 12.5 nmol/l) Precampaign (n=203): 27 (13%) Post-campaign (n=139): 10 (7%)(NS)		
				Paired sample (n=59) Precampaign: 6 (10%) Post-campaign: 7 (12%)(NS)		
				'Present' vit D takers (n=29): 1 (3%) 'Past' vit D takers (n=74): 8 (11%) 'Never' vit D takers (n=33): 2 (6%)		
				H. Vit D supp uptake H1. 1-5 months (during		

Authors Year Country Study Design Quality	Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
				home visiting period): 849 bottles (170 bottles/month) H2. At 6-12 months (when home visits stopped): 75 bottles/month H3. 1 year after campaign stopped: 55 bottles/month H4. 2 years after campaign stopped: 66 bottles/month J. Discharge with Asian rickets and osteomalacia from Glasgow hospitals: no data on women No. of patients (0-16+ years) Pre-campaign:8 Post-campaign: 2		

Authors Year Country Study Design Quality		Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Dunnigan et al. 1985) Glasgow (55.9° N), Scotland Uncontrolled before and after campaign survey Evidence level: 2– Associated reference (Dunnigan 1981)	Asian children 0 to 18 years of age (children of all ethnic groups up to age 5 and Asian children up to age 18) Target population; Asian communities in Glasgow (estimated population 16,000, including 3230 school children)	Study Question: What are the effects of health education to Asians on prevention of vitamin D deficiency in children, supported by provision of free vitamin D supplements on demand? Statistical Analysis: Analysis of before and after study outcomes	The Glasgow rickets campaign (1979-1983) Components of interventions: 1. Free vit D supplements (drops to young children up to aged 3 years, tablets and syrup to children aged 3 to 18 years) on demand. Dose recommended: 10 ug/day 2. A 12-month health education programme by the health education unit directed at the Asian community and at schools with a high proportion of Asian pupils Organisation of campaign: 1. A programme of in-service training provided for community nurses, midwives, health visitors, dietitians, clinical medical officers and general practitioners 2. Distribution of professional fact sheets explaining the policy and clinical features of Asian rickets prepared by the health education unit, via Press Articles for Asian Newspapers, community newsletters, the sound cartoon 'In Place of the Sun' and stills, and posters displayed at Asian Meeting places. 3. Distribution of a simple fact sheet to the Asian community 4. A series of meetings on Asian rickets with leaders of the Asian Social and religious groups. The Glasgow Community Relations Council	(January/May)	Maybe applicable to UK populations. However, insufficient corroborative details on the intervention	The Glasgow Rickets Campaign was carried out in 1979-1983. Possible confounders: No control group Sampling bias Age Place of birth (country of origin) Dress habit Time spent out of door (sunlight exposure) Extent of previous knowledge Language barriers Seasonal variation Dietary change Spontaneous recovery

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
			participated No report of details of interventions relating to -structure and content of health education -characteristics of health professionals who delivered the programme - site/setting of intervention - duration/intensity of intervention - harmful effects - views of participants - specific issues when working with minority ethnic groups	All groups Pre-campaign:15.5 (95% CI 4.5 to 55.0) Post-campaign: 21.0 (95% CI 6.8 to 67.5) (P<0.007) B. % of abnormal X ray appearances Precampaign: 22/181 (12%) Postcampaign: 19/255 (7.5%)(NS) C. % of severe rickets Precampaign: 11/181 (6%) Postcampaign: 5/255 (7.5%)(p<0.05) D. No. of discharge from hospital with nutritional rickets D1. Age 0-4 years Precampaign (1978- 79): 3 Postcampaign (1978- 79): 3 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 13 Postcampaign (1978- 79): 2200 Postcampaign (1978- 79): 2200 Postcampaign (1980- 84): 3300		

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Save the	Asian	Study Question:	A health education	Average knowledge	Maybe applicable	A non-peer reviewed
Children Fund 1983)	communities with a prevalence of	What are the effects of health	programme to explain the nature of rickets and the role	scores/person of rickets and	across a broad range of populations and	report published by the SCF
1903)	vitamin D	education to Asians	of vitamin D in its prevention.	osteomalacia:	settings, assuming it is	SCF
UK	deficiency	on prevention of	Included in the message was	Exl: 18.0	appropriately adapted	Detailed description of the
on	denoioriey	vitamin D	that Vitamin D can be	ExII: 14.36	to focus on pregnant,	organisation and process
	A nationwide	deficiency?	obtained from sunlight, diet	C: 6.85	postpartum,	of the campaign
Controlled before-	intervention		and supplementation.		breastfeeding women	
and-after study	involving Asian	Statistical Analysis:		Total group score:	and women planning a	Target population: Asian
Evidence level:			Campaign organisation:	Exl: 3970/5425 (73%)	pregnancy, and	communities, no specific
2—	Area Health	comparisons of	Stop Rickets Campaign	ExII: 1837/3175	children aged from 0 to	criteria on age and sex)
	Authorities:	outcomes	1. Setting up of a Working	(57.8%)(Ex I vs. Ex II,	5 years, also	
	Barnet Bedfordshire		Group on Rickets comprising representatives of Asian	p<0.05) C: 646/2175 (29.3%)	considering regional difference in sunlight	Insufficient methodological details
	Berkshire		organisations, Commission	(Ex I and II vs. C,	exposure.	lack of contemporaneous
	Birmingham		for Racial Equality, Health	p<0.01)(ExII vs. C,	exposure.	data collection (No pre-
	Bradford		Education Council, members	p<0.01)		campaign data for
	Brent and Harrow		from NHS and the Save the	P		experimental groups, no
	City and East		Children Fund (SCF).	Frequency of mean		pos-campaign data for
	London			scores:		control group)
	Dartford and		2. DHSS provided the	Above mean		
	Gravesend		secretariat and the Chairman	Exl: 176		
	Dudley		2. Compains managed by	ExII: 89		Conformations
	Ealing Hammersmith and		<ol> <li>Campaign managed by SCF</li> </ol>	C: 28		Confounders: Sampling bias
	Hounslow		SCF	Below mean		No report of response
	Enfield and		3. Appointment of a campaign			rate
	Haringey		Director, an Area Health	ExII: 38		Language barriers
	Hertfordshire		Education Officer (who	C: 59		Likelihood of
	Hillingdon		speaks Hindi, Urdu, Gujarati			'contamination' translation
	Kirklees		and Punjabi), supported by a	Total scores for each		competency
	Liverpool		secretary	component of		
	Leicestershire			questionnaire:		The evaluation analysis
	Manchester		4. Use of a leaflet supplied by the Health Education Council	1. Symptoms Exl: 72.4%		was conducted without
	Nottinghamshire Sheffield		– 'Your Child Needs Vitamin	Exil: 72.4% Exil: 59.3%		funding or researchers with a specific brief.
	Staffordshire		D'.	C: 28.5%		
	Walsall			0. 20.0 /0		
	Wolverhampton		5. Development of training	2. Cause		
			material and literature by SCF			
	(Estimated Asian		for NHS staff and Asian	ExII: 68.8%		
	population:680,00		leaders. A special campaign	C: 32%		
	0)		logo incorporating the 'sun			
			and a spoon'.	3. Prevention		

Authors Year Country Study Design	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
Quality				Exl: 67.6%		
			6. Identification of and	ExII: 40.7%		
			preliminary approach made to	C: 13.4%		
			local Asian communities			
			5 5 5	4. Treatment:		
			Census data. An updated list	Exl: 92.8%		
			of Asian organizations was compiled including a register	ExII: 88.9% C: 86.4%		
			of Asian places of worship in	0.00.4%		
			launch areas. Letters from the	5 Information source		
			Campaign Director sent with	TV		
			copies of NHS pack for health			
			professionals (health	ExII: 64%		
			education officers, health	C: 87%		
			visitor training centres and	Radio		
			midwifery schools) and copies			
			of 'Asian Leaders' Pack' were sent to various national and	ExII: 38% C: 15%		
			local community	Newspaper		
			organizations, community	Exl: 7%		
			relations officers, English as a			
			Second Language classes	C: 6%		
			and Industrial Language	Doctor		
			Training Units, explaining the	ExI: 7%		
			aims and scope of the	ExII:30%		
			campaign.	C: 6%		
			7. Making of the campaign	Health Centre ExI: 8%		
			film by a commercial film	Exil: 31%		
			company, involving the	C: 10%		
			District Dietitian and Asian	Hospital		
			families. Media involvement	ExI: no data		
			with expertise provided by the			
			SCF. – meeting with National	C: 2%		
			and Asian press editors (36	Leaflets		
			ethnic newspapers), radio and TV to promote the campaign.	Exi: 8% Exii: 23%		
			i v to promote the campaign.	C:4%		
			8. Address by the campaign	Poster		
			Director to various groups in	ExI: 3%		
			launch areas	ExII: 20%		
				C: 4%		
			9. Consultation with the	Friend		
			community relations councils	ExI: 6%		

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
			languages spoken; also	ExII: 17% C: 6% Talk ExI: 24% ExII: 2% C: no data School ExI: 2% ExII: no data C: 4% Reports of rise in vit D supplement uptake in the first quarter: 16% in Liverpool 11.3% in Birmingham 17% in Bradford dropped to pre- campaign level in the following quarter		

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
			community health doctors, health visitors, school and district nurses, teachers and social workers. Separate briefing for GPs. 16. Post launch visits to			
			women's organisations, supported by the Asian Leaders' Pack to explain the nature and prevention of rickets and osteomalacia. Permission sought to speak to congregations at temples, mosques and gurdwaras to reach large audiences.			
			17. Informal meetings with Asian women to identify unofficial 'opinion leaders' for their influence to pass on what they learnt to other women.			
			18. Where there is objection to a woman speaking in a mosque made by senior members of the religious community, male doctors would give the talks and hold discussions.			
			19. Campaign meetings/visits also to English as a Second Language groups, Asian employers and factories which had substantial numbers of Asian women working.			
			20. Further visits by the Director to antenatal and maternal and Child clinics			

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
Quality			<ul> <li>21. Use of unemployed Asians, under the manpower Service Commission's Community Enterprise Programme, to act as liaison workers between health professionals and the community at home visits and talks in places of worship.</li> <li>22. Two radio jingles were introduced based on Hindi/Urdu folk rhymes: 'Give your child vitamin D' and 'Using the National Health Service', and a new video commercial on 'Give your child vitamin D'.</li> <li>23. Regular showing of the film 'Growing Day by Day', posters in Asian shops and campaign leaflets in clinics, GP surgeries, temples and gurdwaras.</li> <li>24. Care taken to avoid criticism of traditional Asian diets.</li> <li>25. Based on feedback from Asian mothers, a new leaflet 'Why You Need Vitamin D' was produced to replace the</li> </ul>			
			old one 'Your Child Needs Vitamin D'			

Study Design Quality		luestion		Main Results	Applicability to UK populations and settings	Confounders & Comments
A survey (??Before and and Asian ac 19 -70+ 'Before' 178 Asia adults 6 after study) )	- 18 years What a effects dults aged educator years on previtamin study: deficie ans (112 66 children Statist Before tudy: 262 (165 103	are the s of health ation to Asians evention of in D ency? tical Analysis: e and after	on the beneficial effects of adequate exposure to sunshine. Increased consumption of foods containing vitamin D, both natural and fortified, was encouraged. Advice to take supplemental vitamin D preparations on a regular basis was not included in the campaign and no selective food fortification was introduced. (Limited information available on the details of this campaign and no published		limited applicability to UK populations and settings due to insufficient data available about the intervention.	This study is primarily a survey of the prevalence of vitamin D deficiency in 1980. The author compared the 1980 data with data obtained 10 years earlier (1970) from self-referred participants. In the interim period of 10 years, an intervention in the form of a health education campaign was instigated by the author but no details about the methodology of this campaign were available. The comparisons were between two different groups of Asians: a group in 1970 and another group in 1980. There was no control group. The two groups were satisfactorily matched in age and sex. However, the 1970 group was self-referred and the 1980 group was partly self-referred and partly selected randomly. The author went on to analyse/compare biochemical parameters between Asians and Caucasians in Rochdale in 1980. It is not possible to ascertain whether the findings were due to the campaign. Possible confounders:

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
				results tabulated): 1970:10 1980: 8 C. Between Asians and Caucasian children in 1980 C1. Mean serum 25- OHD levels: Asian boys: $25.4\pm17.3$ nmol/l Asian girls: $18.6 \pm 10.4$ nmol/l Caucasians: $77.3 \pm$ 17.7 nmol/l (p<0.001) C2. proportion of children with mean serum 25-OHD levels below 12.5 nmol/l: Asian boys: 22% Caucasian children: lowest 25 OHD levels was 38.5 nmol/l D. Between Asians and Caucasian adults in 1980 D1. Mean serum 25- OHD levels: Asians: $20.3 \pm 14.5$ nmol/l (No difference between Asian men and women) Caucasians: $52.2 \pm$ 27.4 nmol/l (p<0.001) D2. proportion of adults with mean serum 25-OHD levels below 12.5 nmol/l: Asian men: $35\%$ Asian women: $33\%$ Caucasians: 0		Lack of sufficient data on the intervention Unequal groups, sampling bias No control group Sunlight exposure (time spent outdoors) Extent of prior knowledge Spontaneous recovery Dietary changes Dress habit changes Place of birth Length of stay in the UK

Authors Year Country Study Design Quality	Study Population	Research Question	Intervention	Main Results	Applicability to UK populations and settings	Confounders & Comments
(Box 1983) London (51.5° N), UK Quasi-RCT: women allocated by alternation Evidence level 1—	No significant difference in vitamin D intake (2.3 to 2.5 mg/day) and serum 25 OHD	What are the effects of health education and counselling on dietary vitamin D intake and serum 25 OHD levels? Statistical Analysis Comparative analysis between a treatment and a control group	Counselled by Health visitor vs. Non-counselled Counselling by Health Visitor at 6/8 weeks and at 2/4 months of pregnancy Components of the intervention: 1. Setting: antenatal clinic 2. Advice given: At 1st visit (6/8 weeks) Food sources rich in vitamin D Reinforce message with samples of food and proprietary brands Maximise exposure to sunlight Serum 25 OHD levels measured At 2nd /3rd visit (2/4 months) Women questioned about understanding of advice previously given Advice reinforced Serum 25 OHD levels measured at 3rd visit 3. Strategy Women encouraged to bring their mothers-in-law to clinic, as the latter usually make decision about the family's diet Use of Hindu, Muslim and Sikh-speaking receptionists as interpreters	Mean reported dietary vitamin D intake (mg/day) At 2 months Counselled: $2.8 \pm 1.2$ Non-counselled: $2.0 \pm 0.8$ (NS) At 4 months Counselled: $4.1 \pm 1.5$ Non-counselled: $2.7 \pm 0.8$ (p<0.05) Mean serum 25 OHD levels (ng/ml) At 4 months (May- June) Counselled: $5.1 \pm 1.5$ Non-counselled: $4.9 \pm 0.8$ (NS) Difference between 1st and 2nd sample Counselled: $0.07 \pm 0.06$ Non-counselled: $0.15 \pm 0.07$ (p~0.02)		Quasi-RCT: women allocated by alternation at clinic Published in 1983 Small sample Amount of sunlight exposure and body coverage as confounders

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