EVIDENCE SUMMARY TABLE 3b: INTERVENTIONS TO PREVENT WEIGHT GAIN, IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVE DIET AND INCREASE ACTIVITY LEVELS IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (PREGNANCY)

SUMMARY

Two studies (one RCT and one CBA) were included that aimed to prevent excessive weight gain during pregnancy and were published in 2001 and 2002. One further CCT was included that aimed to test the hypothesis that continuing a regular regimen of recreational exercise alters the time specific rate of maternal weight gain and subcutaneous fat deposition during pregnancy. The CBA study was conducted in New York and followed women from early pregnancy to 1-year postpartum (Olson 2004). The RCT was conducted in Pittsburgh and followed women from prior to 20-weeks gestation to 8-weeks postpartum (Polley 2002). The CCT was conducted in Cleveland and followed women from pre-pregnancy to 37-weeks gestation (Clapp 1995). All of the studies reported weight change; one reported dietary and PA outcomes (Polley 2002). The CBA study included an intervention group that had their gestational weights monitored and received education about appropriate weight gain during pregnancy and healthy eating and exercise advice, compared with a historical control group. The RCT included an intervention group that received advice about weight gain during pregnancy and a diet substituting high-fat 'fast foods' with fruit and vegetables and increasing moderate exercise (walking). This intervention was a stepped care approach where women received additional sessions and behavioural goals were increasingly structured should she exceed recommended levels of weight gain at any time during the pregnancy, compared with standard nutritional counselling. The CCT compared participants who continued with the same regular exercise as before pregnancy to those who voluntarily stopped regular exercise. Most of the intervention participants continued to exercise at least three times per week for 30 min or more at an intensity >50% VO_{2max} throughout pregnancy to 37th week.

A Cochrane systematic review of diet in pregnancy reports that the limited evidence available suggests that protein/energy restriction of pregnant women who are overweight or exhibit high weight gain is unlikely to be beneficial and may be harmful to the developing fetus. Only three studies were included, two in Scotland that were both published prior to 1990, one in obese women and the other in women with high gestational weight gain between weeks 20–30.

In the CBA study, 94% were aged between 20–40 years, 75% were of normal pre-pregnancy BMI, 41% were having first baby and 40% had household incomes below 185% federal poverty line. In the RCT, mean age was 25.5 years, 47% were first pregnancies, 57% were unemployed (setting was an obesity clinic for low-income women) just under half of both the control and intervention group women were classed as overweight (BMI 31–34 kg/m^2). One hundred and twenty women were randomised in the RCT and 179 participants in the intervention group of the CBA study were compared with 381 women in the historical control group. In the CCT participants mean age was 31 years, parity ranged from 0 to 2; participants were well educated with family incomes at or above 75th percentile for their state of origin, they were non-smoking White females. There were significantly more homemakers and/or part-time workers in intervention group (31 vs. 14%, $p < 0.05$) and the percentage of women with jobs known to require moderate PA was significantly higher in the control group (39 vs. 23%. $p < 0.05$). Forty-four women in the exercise intervention group and 35 women were in the control group. Baseline body mass (before pregnancy) was 58.1 kg in the intervention group and 60.2 kg in the control group. Mean weekly duration of exercise was 172 min and mean exercise intensity was 66% VO_{2max} for all participants at baseline.

Evidence of efficacy for weight management/reduction

All three studies reported weight change. The CBA study demonstrated that the diet and exercise intervention reduced the risk of excessive gestational weight gain in the low-income subgroup only. Low-income women who received the intervention had a significantly reduced risk of excessive gestational weight gain (OR 0.41, 95% CI 0.20, 0.81); overweight women within this subgroup were at significantly reduced risk of retaining more than 2.27 kg at 1-year postpartum (OR 0.24, 95% CI 0.07, 0.89).

The RCT of diet and exercise using a stepped care approach was effective in reducing the frequency of excessive weight gain in normal weight women (33% intervention vs. 58% control), with the intervention having no significant effect among overweight women but a trend in the opposite direction. The CCT demonstrated that continuing a regular exercise regimen throughout pregnancy resulted in significantly less total weight gain (13.0 [SD 0.5] vs. 16.3 [SD 0.7] kg, $p < 0.0001$). Increases in the sum of skinfold thicknesses were 22 ± 2 and 31 ± 2 mm intervention vs. control at 37 weeks. The intervention did not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but decreases both in late pregnancy. However, overall pregnancy weight gain remains well within the normal range.

Within the Cochrane systematic review (Kramer 2003) of diet during pregnancy, three trials involving 384 women were included. Both Campbell trials (UK) reported that energy/protein restriction was associated with a significant reduction in weekly maternal weight gain, although the magnitude of the reduction was much larger in the 1975 trial (random effects weighted mean difference [WMD] –254.81 [95% CI –436.56, –73.06] g/week). The two trials reporting on birth weight (Campbell 1983; Badrwai 1993) yielded highly (and statistically significantly) heterogeneous results, with Campbell 1983 reporting virtually no effect of the intervention (WMD 6.00 [95% CI –121.55, +133.55] g) but Badrwai (1993) finding a large significant adverse effect (WMD –450.00 [95% CI –624.72, 275.28] g). Postpartum weight retention was not reported.

Evidence of efficacy for diet/physical activity outcomes

The RCT reported a lack of significant effect of the intervention on changes in intake of high-fat foods and changes in exercise level from recruitment to 30 weeks were not related to treatment condition or BMI.

Evidence of corroboration in the UK

Although none of the individual studies was conducted with the UK, the interventions could be implemented in the UK. Two studies published in 1975 and 1983 and included in the review of diet in pregnancy (Kramer 2003) were conducted in Scotland.

EVIDENCE TABLE 3b. INTERVENTIONS TO PREVENT WEIGHT GAIN IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (PREGNANCY)

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
Kramer 2003 Cochrane systematic review 1+	Pregnant women	Energy and protein intake in pregnancy. Review of the effects of advice to increase or reduce energy or protein intake, or of actual energy or protein supplementation or restriction during pregnancy on energy and protein intakes, gestational weight gain and the outcome of pregnancy. Various follow-up Campbell 1975 intervention included 1200 kcal (5.02 MJ)/day low-carbohydrate diet from 30 weeks gestation compared with normal diet. Campbell 1983 intervention involved 1250 kcal (5.23 MJ)/day diet in obese women compared with control. Badrwai intervention involved 1500–2000 kcal	Three trials involving 384 women were included. Both Campbell trials reported that energy/protein restriction was associated with a significant reduction in weekly maternal weight gain, although the magnitude of the reduction was much larger in the 1975 trial (random effects WMD –254.81 [95% CI –436.56, –73.06] g/week). Energy/protein restriction had no effect on either (proteinuric) pre-eclampsia or pregnancy-induced hypertension (with or without proteinuria), although the small number of trials and participants provides inadequate statistical power to exclude a small effect. The two trials reporting on birth weight (Campbell 1983; Badrwai 1993) yielded highly (and statistically significantly) heterogeneous results, with Campbell 1983 reporting virtually no effect of the intervention (WMD 6.00 [95% CI –121.55, +133.55] g) but Badrwai (1993) finding a large significant adverse effect (WMD –450.00 [95% CI –624.72, –275.28] g).	This review just focuses on one element of the Cochrane review: evaluation of low-energy diets in pregnant women who are obese or have high gestational weight gain. Two Campbell studies were conducted in Scotland, one in obese women and the other in women with high gestational weight gain between weeks 20–30. Both were conducted prior to 1990.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
		(6.28–8.37 MJ)/day diet in obese Egyptian women compared with normal WHO-recommended diet;	These large differences in results could reflect either differences in study samples (Scotland vs. Egypt) or differences in the degree of energy/protein restriction achieved. Only Campbell (1983) reported results bearing on gestational duration; the results appear to exclude an important adverse effect of dietary restriction (WMD in mean gestational age +0.25 (95% CI –0.17 to +0.67) weeks). Other outcomes, including fetal/infant mortality and other measures of maternal morbidity (e.g. Caesarean section) or postpartum weight retention, have not been reported. The limited evidence available suggests that protein/energy restriction of pregnant women who are overweight or have high weight gain is unlikely to be beneficial and may be harmful to the developing fetus.	
Olson et al. 2004 CBA (historical control) 2++ **Aim:**	**Eligibility criteria:** Women with normal (19.8–26.0 kg/m^2) and high (26.1–29.0 kg/m^2) BMI entered prenatal care before third trimester, ≥18 years old at delivery, no medical condition	**Intervention:** Graphic design of the Institute of Medicine gestational weight gain grid, separate colour-coded grid was developed for of the four pre-pregnancy BMI	**Lost to follow-up:** Not reported; 21 excluded from intervention group and 22 excluded from control group. Details of the historical control group and recruitment details are described elsewhere in studies by Kendall et al. (2001) and Hinton & Olson	Twelve women who participated in historical control group also participated in prospective intervention group. Bias was detected in the historical control self-reported pre-pregnancy

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
To evaluate the efficacy of an intervention to prevent excessive gestational weight gain.	that might impact body weight, mentally competent, planned to deliver locally and keep the infant, gave birth to live, singleton, term infant. 20% single, 41% having first baby. 96% White **Setting:** Bassett Healthcare (hospital and primary care clinic system serving ten-county area in upstate New York). **Sample size:** Intervention: *n* = 179 Historical control: *n* = 381 **Age:** 94% between 20 to 40 years in both groups. **185% or less below the Federal poverty line:** Intervention: 37.4% Control: 43.3% **Baseline BMI (kg/m^2):** Normal BMI (median, range):	groups, used to determine pre-pregnancy BMI, plotting gestational weight gain (2-hour orientation programme given for interested providers, attendance voluntary with continuing education credits given; patient education component included health check book that contained weight gain and self-monitoring tools; also food guide pyramids and tips for healthy eating and exercise in pregnancy; five × 1-page newsletters (pre-tested in focus groups that included low-income women); postcards sent with newsletters encouraging active participations, asking questions that were answered in next newsletter and prize incentives for sending back postcard. Providers of the intervention included Bassett Healthcare staff and the researchers	(2001). **Gestational weight gain (mean, kg):** Intervention: 14.10 (SD 4.51) Control: 14.80 (SD 4.68), *p* = 0.09 **Proportion of women gaining more than recommended weight:** Intervention: 41% Control: 45%, *p* = 0.3 Low-income women in intervention: 33% Low-income women in control: 52%, *p* < 0.01 Significant difference in excess weight gain within low-income women also seen in overweight and normal BMI groups. **Normal BMI:** Low-income women in intervention: 29% Low-income women in control: 45%, *p* = 0.05 **Overweight:** Low-income women in intervention: 44% Low-income women in control: 72%, *p* = 0.04 No significant effect of intervention detected in high-income women.	weight so weight in both groups was calculated from last prenatal visit where weight was measured. This study had power to detect an effect size of intervention of 90% statistical power to detect a 50% reduction from the observed 71% gaining above the weight range in the historical group, with a 5% false-positive rate using a two-sided test of significance. Within low-income women, there was a 96% statistical power to detect 50% reduction from the observed 52% gaining above the weight range in the historical group with a two-sided 5% false-positive rate.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Intervention: 22.6 (19.8–26.0), *n* = 290 Control: 23.1 (20.0–26.0), *n* = 131 Overweight (BMI median, range): Intervention: 27.2 (26.1–29.0), *n* = 91 Control (historical control group): 27.2 (26.0–29.0), *n* = 48	**Control:** Not reported. **Follow-up:** 12-months postpartum.	**Weight retention at 1-year postpartum (kg):** Intervention: 0.59 (4.74) Control: 1.31 (5.60) **Women retaining 2.27 kg or more at 1-year postpartum:** Intervention: 31% Control: 38%, *p* = 0.14 Low-income and overweight women: Intervention: 25% Control: 55%, *p* = 0.04 High-income and normal BMI: Intervention: 24% Control: 36%, *p* = 0.07 **Diet:** Not reported. **Physical activity:** Not reported. **Author's conclusion:** The intervention reduced the risk of excessive gestational weight gain in the low-income subgroup only. Low-income women who received the intervention had a significantly reduced risk of excessive gestational weight gain (OR 0.41, 95% CI 0.20, 0.81).	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
			Overweight women within this subgroup were at significantly reduced risk of retaining more than 2.27 (OR 0.24, 95% CI 0.07, 0.89) kg.	
Polley et al. 2002 RCT 1+ **Aim:** To determine whether a stepped care behavioural intervention will decrease the percentage of women who gain more than the Institute of Medicine recommendation for gestational weight gain.	**Eligibility criteria:** Low-income women before 20 weeks gestation **Exclusion:** Women underweight (BMI <19.8 kg/m^2), <18 years old, first prenatal visit was above 12 weeks gestation, those with high-risk pregnancy **Setting:** Obstetric clinic for low-income women at a hospital in Pittsburgh, PA, USA. Age 25.5 (SD 4.8) years, 39% Black, 45% high school or less, 57% unemployed, 47% first pregnancy. **Sample size:** Intervention: *n* = 61 (32 normal weight and 29 overweight) Control: *n* = 59 (33 normal weight and 26 overweight)	**Intervention:** Delivered by masters and doctoral level staff with training in nutrition or clinical psychology, participants given information on appropriate weight gain during pregnancy, exercise and healthful eating, newsletters mailed biweekly, sent personalised graph of weight gain after each clinic visit, women exceeding weight gain given additional individualised nutrition and behavioural counselling (stepped care approach with increasingly structured behavioural goals if weight continued to exceed recommended levels). Focus on decreasing high fat foods such as 'fast food' items, substituting with fruit and vegetables, increasing walking and developing a	**Lost to follow-up:** Intervention: *n* = 27 Control: *n* = 19 **Proportion of women gaining more than recommended weight and mean weight gain:** Intervention Normal weight: 33.3%, *n* = 10, 23.6 kg Control Normal weight: 58.1%, *p* < 0.05 *n* = 18, 19.1 kg Intervention Overweight: 59.3%, *n* = 16, 17.7 kg Control Overweight: 31.8%, *p* = 0.07, *n* = 7, 17.3 kg Although intervention significantly reduced percent normal weight women who exceed weight gain goal, intervention had no significant effects on average weight gain from pre-pregnancy to delivery and weight gains were	Randomisation was stratified by BMI category and race. Pre-pregnancy weight was self-reported. Women whose weight exceeded guidelines were given additional sessions No significant effects of race on percentage of women with excessive weight gain (*p* > 0.3). Weight gained before recruitment was strongly related to excessive weight gain (*p* < 0.0001). It is not clear if the study was sufficiently powered to detect a significant effect on weight outcomes with intervention compared with control.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Baseline BMI (kg/m^2): Normal weight Intervention: 22.8 (1.9), *n* = 30 Control: 22.5 (2.0), *n* = 31 Overweight Intervention: 31.4 (6.0), *n* = 27 Control: 34.1 (7.2), *n* = 22	more active lifestyle. Contacted by telephone between clinic visits **Control:** Standard nutritional counselling provided by physicians, nurses, nutritionists and Women, Infants and Children (WIC) counsellors emphasising well balanced diet and multivitamin/iron supplement. **Follow-up:** 8-weeks postpartum (from prior to 20 weeks gestation).	comparable between Black and White women. **Weight retention at mean 8-weeks postpartum:** Intervention Normal weight: 4.4 (SD 5.4) kg Control Normal weight: 6.2 (SD 4.5) kg Intervention Overweight: 3.6 (SD 5.6) kg Control Overweight: 0.3 (SD 7.0) kg Weight retention was strongly correlated with weight gain during pregnancy (r = 0.89, p < 0.001). **Diet:** No effect of intervention on changes in intake of high-fat foods. **Physical activity:** Changes in exercise level from recruitment to 30 weeks were not related to treatment condition or BMI. **Authors' conclusion:** The intervention was effective in	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
			reducing the frequency of excessive weight gain in normal weight women, the intervention had no significant effect among overweight women but the trend was in the opposite direction; the more intensive stepped care element that occurred subsequent to excessive weight regain may have been a less effective component than the prevention component (fewer women in the intervention group exceeded recommended weight gain at any point during their pregnancy (63 vs. 94%);	
Clapp 1995 CBA 2– **Aim:** To test the hypothesis that continuing a regular regimen of recreational exercise alters the time specific rate of maternal weight gain and subcutaneous fat deposition during pregnancy.	**Eligibility criteria:** Normal women with generally active lifestyles who also engaged in regular exercise at or above a basic conditioning level for the primary purpose of health and recreation for at least 6 months and who conceived and experienced a normal pregnancy. Participants were unselected and consecutively enrolled. **Exclusion:** Women with infertility or pregnancy complications. **Setting:**	**Intervention:** Participants continued with same regular exercise as before pregnancy; exercise levels varied widely between but not within participants during pregnancy. Most continued to exercise at least three times per week for 30 min or more at an intensity greater than 50% VO_{2max} throughout pregnancy to 37th week. **Control:** Participants who voluntarily stopped their regular	**Lost to follow-up:** Intervention: *n* = 27 Control: *n* = 19 When covaried for the minor differences in preconceptional weight the rate of weight gain was similar in the control (0.3 kg/week) and intervention groups (0.25 kg/week) through to the 15th week. Between 15th–23rd week and 23rd–30th weeks the rate of weight gain was significantly ($p < 0.05$ and $p < 0.002$) less in the intervention group. Averaging 0.47 vs. 0.57 kg/week in the control group. Although the rate of weight gain decreased between 30 and 37 weeks in both groups, the women in the intervention group continued to gain	Randomisation was stratified by BMI category and race. Not aimed at preventing excessive weight gain in pregnancy. Intervention and control groups were self-selecting Significant important differences at baseline which may confound results.

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	Obstetric clinic, Cleveland, OH, USA. Age 31 (SD 0.3) years, parity ranged from 0 to 2; well educated (mean 17.3 years), family incomes at or above 75th percentile for their state of origin, non-smoking White; significantly more homemakers and/or part-time workers in intervention group (31 vs. 14%, $p < 0.05$); percentage of women with jobs known to require moderate PA was significantly higher in control group (39 vs. 23%, $p < 0.05$); **Sample size:** Intervention: $n = 44$ Control: $n = 35$ **Baseline body mass: (prior to pregnancy):** Intervention: 58.1 (SD 1.0) kg Control: 60.2 (SD 1.2) kg Mean height for all participants 166.7 (SD 0.6) cm **Mean weekly duration of exercise:** All participants: 172 ± 6 min **Mean exercise intensity:**	exercise regimen because of concern that it would have negative effects on pregnancy, $n = 31$ or reduced it below baseline fitness levels in very early pregnancy, $n = 4$). All participants consumed a balanced diet, reported energy intake rose consistently during pregnancy with no significant differences between the two groups; however, 12 aerobics instructors who were intervention participants had significantly greater energy intake. **Follow-up:** 37 weeks	significantly ($p < 0.001$) less than the controls (0.31 vs. 0.47 kg/week). As a result total weight gain was significantly ($p < 0.0001$) less in the intervention group (13.0 [SD 0.5] vs. 16.3 [SD 0.7] kg). Increases in the sum of skinfold thicknesses were 22 ± 2 mm and 31 ± 2 mm intervention vs. control at 37 weeks. Authors conclude that continuing a regular exercise regimen throughout pregnancy does not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but decreases both in late pregnancy. However, overall pregnancy weight gain remains well within the normal range.	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/comments
	All participants: 66 ± 1% VO_{2max}. **Significant differences at baseline:** Sum of five skinfold thicknesses greater in control group, also subjects who continued to exercise (intervention group) spent 44% ($p < 0.01$) exercising each week than those subjects who stopped (control group) representing average difference in energy expenditure of 600 kcal (2.51 MJ)/week.			

Evidence of corroboration (external validity)

Evidence of salience from studies conducted in the UK

First author	Study population	Research question	Length of follow-up	Main results	Confounders/comments

Evidence for implementation – Will it work in the UK?

Pregnancy Anderson 1995	CCT	Maternity hospital in Aberdeen.	To assess the effect of dietary advice education intervention on nutrient intake during pregnancy.	From booking to 26 weeks gestation.	Intervention participants received information packs on nutrition at time of booking and at 26-weeks gestation, all participants received general pregnancy health guide. Results showed that knowledge about nutrition was significantly higher in the intervention group (magnitude unlikely to make difference in practice), but no significant differences were noted on attitude variables or nutrient intake (fat, energy).