

# Interventions to reduce or prevent obesity in pregnant women: a systematic review

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## Executive summary

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# Executive summary

## Background

The increasing prevalence of obesity is a major health problem: a recent Health Survey for England found that one-quarter of both men (23.6%) and women (23.8%) are obese, with a body mass index (BMI) of  $\geq 30 \text{ kg/m}^2$ . In total, 50% of women of childbearing age are either overweight (BMI 25–29.9  $\text{kg/m}^2$ ) or obese, with 18% starting pregnancy as obese. Currently, 20–40% of women gain more than the recommended weight during pregnancy, resulting in an increased risk of maternal and fetal complications. More than half of women who die during pregnancy, childbirth or the puerperium are either obese or overweight. The maternal complications associated with obesity include miscarriage, hypertensive disorders such as pre-eclampsia, gestational diabetes mellitus, infection, thromboembolism, caesarean section, instrumental and traumatic deliveries, wound infection and endometritis. The fetal risks associated with obesity include stillbirths and neonatal deaths, macrosomia, neonatal unit admission, preterm births, congenital abnormalities and childhood obesity with associated long-term risks. Excessive weight gain in pregnancy is also associated with persistent retention of the weight gained beyond pregnancy in the mother and an increase in obesity in children at 2–4 years. The health risks to the mother and baby of obesity and excessive weight gain pose significant demands on the health-care system, with an increased need for additional care and resources in both primary and secondary care settings.

The antenatal period provides a window of opportunity to deliver weight management interventions as pregnant women are motivated to make changes and there are opportunities for regular contact with health professionals. Although reduction in weight gain or weight loss may be of benefit, there is a potential for harm to the mother or baby as a result of the weight loss itself or as a result of the interventions. The Institute of Medicine (IOM) guidelines describe the optimum weight gain in pregnancy for American women based on their BMI. The guidelines recommend a gestational weight gain of 11.5–16.0 kg in women with normal BMI (BMI 18.5–24.9  $\text{kg/m}^2$ ), of 7.0–11.5 kg in overweight women (BMI 25–29.9  $\text{kg/m}^2$ ) and of 5–9 kg in obese women (BMI  $\geq 30 \text{ kg/m}^2$ ). Current recommendations provide limited information on the magnitude of the benefits and adverse outcomes resulting from weight management in pregnancy.

## Objectives

This health technology assessment (HTA) project was undertaken to evaluate the evidence on dietary and lifestyle interventions to reduce weight or prevent weight gain in pregnancy. The objectives were to:

- determine the effectiveness of various dietary and lifestyle interventions in pregnancy that prevent or treat obesity for maternal and fetal weight (primary objective)
- determine the effectiveness of various dietary and lifestyle interventions that prevent or treat obesity for obstetric antenatal, intrapartum and postnatal outcomes
- evaluate the benefit of the dietary and lifestyle weight management interventions in pregnancy for fetal and neonatal morbidity and mortality

- study the potential short- and long-term adverse effects in mother and baby due to dietary and lifestyle in pregnancy.
- assess the overall strength of evidence across outcomes for effectiveness and harm of interventions.

## Methods

Systematic reviews of the effectiveness and harm of interventions were carried out using a methodology in line with current recommendations. The following databases were searched (1950 until March 2011) to identify relevant studies: MEDLINE, EMBASE, BIOSIS, Latin American and Caribbean Health Sciences Literature (LILACS), Science Citation Index, Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE), HTA database and PsycINFO. Relevant unpublished studies and those reported in the grey literature were searched for in databases including Inside Conferences, Systems for Information in Grey Literature (SIGLE), Dissertation Abstracts and ClinicalTrials.gov. Language restrictions were not applied. The search strategy was developed by including search terms related to 'pregnancy' and 'weight'. The search was limited by filters for 'human studies' and 'study type' (randomised clinical trials and observational trials exclusive of case series and case reports). We designed a separate search strategy in the databases previously described to identify studies on harm by including adverse effects text words and indexing terms to ensure that they were not missed. Study selection was performed by two independent reviewers. First, the electronic searches were scrutinised and full manuscripts of all citations that were likely to meet the predefined selection criteria were obtained. Studies that met the predefined and explicit criteria regarding population, interventions, outcomes and study design were selected for inclusion in the review.

Studies that evaluated any dietary, physical activity or behavioural counselling intervention with the potential to influence weight change in pregnant women were included. Pregnant women who were underweight (BMI < 18.5 kg/m<sup>2</sup>) were excluded. Both randomised controlled trials and observational studies were included. For evaluation of adverse effects, in addition to these, case series were included. The quality of the selected randomised controlled trials and observational studies was assessed based on accepted contemporary standards. The risk of bias of the individual randomised studies was assessed in six domains: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias. Results were summarised as pooled relative risks (RRs) with 95% confidence intervals (CIs) for dichotomous data. Continuous data were summarised as mean difference (MD) with 95% CIs. Separate analyses were performed on randomised and non-randomised data. For meta-analysis of the data in the effectiveness review, non-randomised and observational data were considered only if there was a paucity of randomised trial evidence for interpretation. The chi-squared and *I*<sup>2</sup> statistics were used to assess statistical heterogeneity between trials. If substantial heterogeneity was detected (*I*<sup>2</sup> > 50%), possible causes were explored and subgroup analyses for the main outcomes performed. Subgroups defined a priori were BMI of the women, type of intervention, responders, publication year (last 20 years), study quality and setting. Heterogeneity that was not explained by subgroup analyses was modelled using random-effects analysis, where appropriate. Publication bias was assessed by funnel plots of the log-odds ratios. All analysis was carried out using RevMan 5.0 statistical software (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark).

The relevant obstetric and neonatal outcomes considered to be important to decision-making were identified by a two-round Delphi survey of clinicians. Gestational diabetes, pre-eclampsia,

thromboembolism and maternal admission to the high-dependency unit (HDU) or intensive care were considered to be the critically important clinical outcomes in the evaluation of interventions to prevent or reduce obesity in pregnancy. The critically important fetal outcomes were small-for-gestational-age fetuses, shoulder dystocia, intrauterine death, long-term neurological sequelae and admission to the neonatal intensive care unit. The quality of the overall evidence synthesised for each outcome was summarised using GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology and reported graphically as a two-dimensional chart.

## Results

### *Effectiveness of interventions*

#### Study selection and identification

From 19,583 citations, 88 full papers were selected for assessment of eligibility. A total of 56 experimental studies (40 randomised and 16 non-randomised controlled studies; involving 8842 women) and 32 observational studies (26 cohort and six case-control studies; involving 173,297 women) evaluated the effectiveness of dietary, physical activity and other lifestyle interventions in pregnancy for maternal and fetal outcomes.

#### Quality of the included studies

There was a low risk of bias for blinding for objective outcome assessments (38/40, 95%) and freedom from selective reporting (31/40, 77.5%). Four of the 40 randomised studies (10%) were blinded for subjective outcomes. Half of the studies adequately addressed the issue of incomplete outcome data (19/40). Sequence generation and allocation concealment were adequate in 40% (16/40) and 7.5% (3/40) of studies, respectively, and unclear in the others.

The quality of the included non-randomised studies varied from moderate to low. None of the 16 studies used blinding. More than 70% of the included cohort studies were adequate for representativeness, selection of the cohort, outcome assessment and follow-up. Of the case-control studies, case definition, representativeness, comparability and ascertainment of outcome were adequate in >70%.

#### Effect of interventions on weight-related outcomes

A total of 30 randomised studies reported the effect of interventions on maternal weight and 28 the effect of interventions on fetal weight-related outcomes. Meta-analysis of the 30 studies (involving 4503 women) showed a overall reduction in weight gain in the intervention group of 0.97 kg compared with the control group (95% CI -1.60 kg to -0.34 kg;  $p=0.003$ ). This reduction in gestational weight gain was largest in the dietary intervention group, with a MD of -3.36 kg (95% CI -4.73 kg to -1.99 kg;  $p<0.00001$ ). There was a reduction trend in the number of women in the intervention group exceeding the IOM recommendations for weight gain in pregnancy (RR 0.77, 95% CI 0.42 to 1.42) and BMI at delivery (MD -0.23, 95% CI -1.4 to 0.94) for all interventions.

Meta-analysis of the 28 RCTs including 4573 babies showed a significant reduction in the pooled birthweight estimate of the infants in the intervention group, with a MD of -0.07 kg (95% CI -0.14 kg to -0.01 kg;  $p=0.03$ ) for all interventions. There was a 27% reduction (RR 0.73, 95% CI 0.54 to 0.99;  $p=0.05$ ) in the pooled estimate for the risk of large-for-gestational-age newborn (12 RCTs, involving 3021 newborns). There was no difference in the incidence of low-birthweight or small-for-gestational-age infants between the two groups, with a RR of 0.99 (95% CI 0.76 to 1.29). The studies were homogeneous. The effect was consistently observed with all interventions.

### Effect of interventions on obstetric outcomes

A total of 29 randomised trials evaluated the effect of interventions in pregnancy on obstetric outcomes. Weight management interventions in pregnancy resulted in a significant overall reduction in the incidence of pre-eclampsia (RR 0.74, 95% CI 0.59 to 0.92;  $p=0.008$ ) and shoulder dystocia (RR 0.39, 95% CI 0.22 to 0.70;  $p=0.02$ ). The largest effect was observed with dietary interventions, with a significant decrease in pre-eclampsia (RR 0.67, 95% CI 0.53 to 0.85;  $p=0.0009$ ) and gestational hypertension (RR 0.30, 95% CI 0.10 to 0.88;  $p=0.03$ ). Dietary interventions in pregnancy also resulted in a significant reduction in preterm births (RR 0.68, 95% CI 0.48 to 0.96;  $p=0.03$ ) and a trend towards a reduction in the incidence of gestational diabetes (RR 0.52, 95% CI 0.27 to 1.03). There were no overall differences in the rates of caesarean section (RR 0.93, 95% CI 0.85 to 1.03) or induction of labour (RR 1.12, 95% CI 1.00 to 1.26) between the groups for the interventions.

The mean gestational age of delivery was slightly reduced in the pooled estimate of all interventions, but was not statistically significant (MD  $-0.03$  weeks, 95% CI  $-0.13$  weeks to 0.07 weeks).

### Effect of interventions on fetal and neonatal morbidity and mortality

Ten randomised studies (3375 babies) evaluated fetal and neonatal morbidity and mortality. There were no differences in the rates of admission to the neonatal intensive care unit, respiratory distress syndrome, neonatal hypoglycaemia, stillbirths and neonatal deaths or in Apgar scores at 1 minute and 5 minutes after delivery for all interventions. No differences were observed for stillbirths or perinatal deaths in the included non-randomised trials.

### Adverse effects of interventions

A total of 26 studies involving 468,858 women were selected from 14,832 citations to evaluate the adverse effects of interventions. They included two randomised controlled trials and 24 observational studies (19 cohort and five case-control design).

Most of the data on adverse effects from dietary interventions were derived from studies on extreme diet and famine. There was an increase in the rate of neural tube defects and cleft lip and palate in pregnant women practising extreme forms of dieting and on high-glycaemic index diets. Starvation in pregnancy was associated with an increased incidence of metabolic syndrome, dyslipidaemia, coronary artery disease and hypertension. No significant maternal or fetal adverse effects of physical activity in pregnancy, such as cord abnormalities, threatened miscarriage, meconium-stained liquor, abnormal fetal heart rate pattern, maternal sepsis or chorioamnionitis, were observed.

### Conclusions

Dietary and physical activity interventions in pregnancy are effective at reducing maternal weight gain in pregnancy (evidence quality was moderate) at birth compared with usual care. Typical dietary interventions include a balanced diet consisting of carbohydrates, proteins and fat and maintenance of a food diary. Typical physical activity-based interventions include light-intensity resistance training, weight-bearing exercises and walking for 30 minutes. They do not increase the risk of small-for-gestational-age or low-birthweight babies (evidence quality was high). Interventions that are mainly based on diet are effective at reducing obstetric outcomes such as gestational hypertension, pre-eclampsia, and shoulder dystocia and trend towards reduction in gestational diabetes (evidence quality was low to high). There were no changes in other neonatal morbidity or mortality outcomes with the interventions.

## Implications for practice

The evidence is in favour of employing dietary interventions as opposed to other methods to reduce gestational weight gain in pregnancy and obstetric complications in both normal-weight and obese or overweight women. Mothers should be informed about the degree of benefit gained with weight management measures, especially diet, for various outcomes. Women can be reassured that there is no evidence of harm associated with the interventions to manage weight in pregnancy.

## Recommendations for further research

Individual patient data meta-analyses will add value to the study-level data analysis reported here. There is a need for further research to identify the facilitators and barriers to the implementation of the interventions in various health-care settings. For interventions to be taken up by the women and provided by staff, the acceptability of the various components needs to be ascertained. If interventions are introduced on the basis of their effect on maternal weight change, there needs to be an evaluation alongside of their effects on other outcomes, as well as adverse outcomes. If randomised controlled trials are undertaken they should focus on clinically relevant outcomes.

[Note: The results of this systematic review for effectiveness of weight management interventions in pregnancy includes only studies published before March 2011. The findings with the updated search (until January 2012) can be accessed at *BMJ* 2012;**344**:e2088 doi10.1136/bmj.e2088.]

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## Publication

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