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Systematic review

Interventions during pregnancy to reduce excessive gestational weight gain: a systematic review assessing current clinical evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system

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Background Excessive weight gain during pregnancy is common in developed countries and increases the risk of complications during pregnancy, delivery and the postpartum period, which can affect both maternal and fetal outcome. Interventions to reduce excessive gestational weight gain have previously not been systematically evaluated using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system.

Objectives To determine whether published trials of interventions to reduce excessive gestational weight gain are of sufficient quality and provide sufficient data to enable evidence-based recommendations to be developed for clinical practice in antenatal care.

Search strategy A literature search was conducted in the scientific databases PubMed, Cochrane Library, Cinhal and Pedro, and the reference lists of relevant articles were reviewed. The literature search was concluded on 15 August 2009.

Selection criteria All randomised controlled trials (RCTs) were considered for inclusion. As the number of published RCTs was limited, we also considered for inclusion all nonrandomised intervention studies that included a control group. Systematic reviews were examined to identify additional original studies.

Data collection and analysis Two reviewers independently assessed the quality of the methods and results of all included articles. Extracted data were classified using the GRADE system.

Main results Four intervention studies with a randomised controlled design and four intervention trials with a nonrandomised controlled design met the inclusion criteria. As a consequence of important limitations in study design, inconsistency and lack of directness, the overall quality of evidence was judged to be very low using the GRADE system.

Authors' conclusions The results of published intervention trials are of insufficient quality to enable evidence-based recommendations to be developed for clinical practice in antenatal care.

Keywords Gestational weight gain, pregnancy, prevention of obesity.

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Introduction

Excessive weight gain during pregnancy is common in developed countries and increases the risk of a variety of complications during pregnancy, delivery and the postpartum period, which can affect both maternal and fetal outcomes.[1–5] Excessive gestational weight gain (GWG) is also associated with higher postpartum weight retention and is therefore a factor contributing to the prevalence of overweight and obesity among women and the increasing the long-term risk of weight-associated diseases.[6,7] Recent publications also suggest a correlation between high maternal weight gain during pregnancy and increased risk of childhood adiposity and morbidity in the child.[8,9]

Recent evidence suggests that the Institute of Medicine (IOM) recommendations[10] for GWG, which have guided clinical practice for nearly 20 years, may have been too liberal and, in particular, that overweight and obese women might benefit from even lower recommended weight gain limits to improve maternal and fetal outcomes.[3,11] The IOM guidelines were recently revised, and new recommendations for total weight gain during pregnancy and the rate of this weight gain were issued in May 2009.[12]

As the majority of pregnant women already currently exceed existing recommended limits for weight gain, interventions to reduce such excessive weight gain are needed.

Pregnancy is a period in life when women are likely to be motivated to make lifestyle changes, so interventions to reduce excessive weight gain during pregnancy could also be beneficial in promoting a healthy lifestyle in the long term. However, any intervention undertaken during pregnancy should be based on clinical evidence of a favourable balance between benefits and risks to ensure the well-being of both the pregnant woman and her fetus. There are currently no evidence-based guidelines regarding effective interventions to support pregnant women and facilitate their achievement of recommended weight goals.

The primary objective of this review was to determine whether published trials of interventions to reduce excessive GWG are of sufficient quality, in terms of their methods and results, to enable evidence-based recommendations to be developed for clinical practice in antenatal care.

Methods

Specific research question of the systematic review

In healthy pregnant women, what is the effect of a particular behavioural or educational intervention during pregnancy on excessive GWG compared with standard maternity care, and what is the quality of the evidence?

Search strategy

The literature search was conducted in the following databases: PubMed, Cochrane Library, Cinhal and Pedro. The reference lists of relevant articles were searched and additional studies were included if they fulfilled the inclusion criteria. Only articles written in English or any of the Scandinavian languages were considered. No limit as to time of publication was set. Studies with a qualitative design were not included. The following search terms were used in different combinations: gestation, weight gain, obesity, pregnancy, physical activity, exercise, intervention and prevention. We also searched the Clinical Trials Registry of the US National Institutes of Health but made no other attempts to identify unpublished literature. The last literature search was performed on 15 August 2009.

Criteria for inclusion

Study design

We considered all randomised controlled trials (RCTs) for inclusion. Because of the limited number of published RCTs in the field of interest, we also considered all non-randomised controlled trials for inclusion. Study size was not used as a limiting criterion for inclusion. Systematic reviews were assessed for quality and relevance, and if found sufficient for our purpose, the original studies included were identified and assessed.

Study population

To be included, studies were required to have recruited participating women before the third trimester of pregnancy. No limitations in relation to age, ethnicity, socioeconomic status or body weight at enrolment were set. Study populations consisting only of women with diabetes mellitus in any form were excluded.

Intervention

No limitations as to mode of intervention or who delivered the intervention were set. Weight-reducing pharmaceutical or surgical interventions were not included in this review.

Comparison

Only studies comparing interventions with standard maternity care were considered for inclusion.

Outcome measures

Any of the following outcome measures were accepted for inclusion:

- Total GWG (kg/lb).
- Rate of GWG (kg/lb per week or kg/lb per trimester).
- Proportion of women exceeding IOM weight gain recommendations.

Studies were accepted for inclusion regardless of whether GWG was reported as a primary or a secondary outcome.

Quality assessment

All original studies matching our search criteria were initially evaluated in abstract form; at this stage, study design, study size and outcome measures were not assessed. Studies found to be relevant were retrieved in full text form, and the quality of their methods and results was assessed by two reviewers independently using the QUOROM statement checklist.[13]

Extracted data were used to determine the strength of evidence as per the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system.[14] The quality of systematic reviews was assessed using the AMSTAR instrument.[15]

Results

Eleven intervention trials were initially identified and considered for inclusion. After full text assessment, two studies were excluded because they lacked a control group.[16,17] One study was excluded because it focused on the effects on blood pressure of a low-sodium diet in pregnancy.[18]

Three intervention studies with a randomised controlled design and one study with a quasi-randomised design qualified for inclusion in this review (in total, 306 study patients). Three were conducted in the USA and one in Denmark. Details of the RCTs included are given in Table 1.

Four intervention studies with a nonrandomised controlled design met the inclusion criteria and were assessed accordingly (in total, 1232 study patients). The nonrandomised studies included were conducted in Finland, Sweden, Canada and the USA. Details of the nonrandomised trials included are given in Table 2.

Two systematic reviews of RCTs were identified.[19,20] The review by Kuhlman *et al.* assessed interventions to reduce both GWG and postpartum weight retention. This review

Table 1. Details of RCTs

Study	Design	Population	Intervention	Control	Outcome	Results
Polley *et al.* 2002	Randomised controlled trial.	Low-income population. USA BMI > 19.8 Age > 18 years *n*(I) = 57 *n*(C) = 53	Stepped-care behavioural intervention. By-mail education. Personalised graph of weight gain.	Standard maternity care.	Proportion of women exceeding IOM recommendations.	Significant decrease in normal weight women exceeding IOM recommendations (58 versus 33%, $P < 0.05$). Opposite trend among overweight women (32 versus 59%, $P = 0.09$).
Wolff *et al.* 2008	Randomised controlled trial.	Caucasian, non smoking Denmark. BMI > 30 Age > 18 years Non smoking *n*(I) = 23 *n*(C) = 27	Individual dietary consultations on 10 separate occasions during pregnancy	Standard maternity care.	Gestational weight gain (kg).	Significantly less total weight gain in the intervention group ($P = 0.002$).
Bechtel-Blackwell D. 2002	Quasi-randomised controlled trial.	African-American women. USA Age 13–18 years *n*(I) = 22 *n*(C) = 24	Patient education. Group sessions. Repeated nutritional assessment.	Standard maternity care. Repeated nutritional assessment.	Weight gain (lb) per trimester. Weight retention 6 weeks postpartum (lb).	1st trimester; significantly less ($P < 0.000$) weight gain in group with intervention; 2nd trimester; no difference; 3rd trimester; Significantly higher ($P < 0.006$) weight gain.
Asbee *et al.* 2009	Randomised controlled trial.	USA BMI < 40.5 Age 18–49 years *n*(I) = 57 *n*(C) = 43	Consultation with dietician in early pregnancy. Information about IOM recommendations and weight grid. Encouraged to exercise.	Standard maternity care.	Proportion of women exceeding IOM recommendations.	No significant difference in adherence to IOM recommendations ($P = 0.21$).

C, control group; I, intervention group.

Table 2. Detail of nonrandomised controlled trials

Study	Design	Population	Intervention	Control	Outcome	Results
Kinnunen *et al.* 2007	Nonrandomised, controlled trial.	Primipara Finland Age > 18 years *n*(I) = 49 *n*(C) = 56	Individual counselling concerning diet and physical activity.	Standard maternity care	Total weight gain (kg). Proportion of women exceeding IOM recommendations.	No significant difference in total GWG ($P = 0.77$). No significant difference in proportion exceeding IOM recommendations ($P = 0.053$).
Olson M *et al.* 2004	Historical control group. Nonrandomised.	BMI 19.8–29.0 USA. Age > 18 years *n*(I) = 179 *n*(C) = 381	Education of healthcare providers. Weight gain grid. By-mail patient education.	Standard maternity care	Proportion of women exceeding IOM recommendations.	No overall significant difference in GWG ($P = 0.3$). Significant difference in GWG in 'low-income' subgroup ($P = 0.01$).
Claesson *et al.* 2007	Nonrandomised, controlled trial.	BMI > 30 Sweden *n*(I) = 155 *n*(C) = 193	Patient education and motivation. Frequent individual sessions. Aqua aerobic exercise.	Standard maternity care	GWG (kg).	Significantly less weight gain in the intervention group ($P < 0.001$).
Gray-Donald *et al.* 2000	Nonrandomised. Historical control group.	Cree Indian population. Canada. *n*(I) = 112 *n*(C) = 107	Patient education. Individual sessions. Dietary assessment. Community activities focused on nutritional advice. Exercise groups.	Standard maternity care. Dietary assessment.	Weight gain (kg)/week.	No significant difference in rate of weight gain or total GWG between groups ($P = 0.29$).

C, control group; I, intervention group.

included only one study, by Polley *et al.*,[21] that met our inclusion criteria, and that study was also identified in our literature search. The other review, by Dodd *et al.*,[19] which focused on interventions in overweight and obese women, identified the same study[21] and a study of women with gestational diabetes.[22]

Population characteristics

Use of body mass index (BMI) as an inclusion criterion varied among the studies. Two studies only included women with BMI ≥ 30 kg/m^2.[23,24] Three studies reported no inclusion criteria for BMI.[25–27] One study included only women with prepregnancy BMI 19.8–29.0 kg/m^2,[28] one study excluded women with BMI < 19.8 kg/m^2,[21] and another study excluded women with BMI > 40.5 kg/m^2.[29] The age limit for participating women was set at >18 years in five of the included studies.[21,24,26,28,29]. Two studies reported no age limit for inclusion[23,27] and one study focused on women aged 13–18 years.[25] The ethnicity of the women included also differed among the studies. Four studies were conducted in the USA. However, one included only African–American women,[25] in one the participants were recruited from a low-income population[21] and two reported no inclusion criteria related to ethnicity.[28,29] In one study the participants were recruited from a Canadian Cree Indian population.[27] Three studies included women from the Nordic countries.[23,24,26]

Intervention characteristics

The following modes of intervention were used in the original studies included in this review:

- Dietary counselling (individual or group sessions).
- Nutritional education.
- Behavioural intervention.
- Education of women by mail.
- Use of individual weight gain grid.

- Physical activity (individual or group sessions).
- Education of women and/or healthcare providers.

The interventions used in each included study are described in Tables 1 and 2. The interventions used in the trials varied in frequency, duration and intensity and were sometimes used in combination.

Control group characteristics

Six studies reported data for control groups receiving standard maternity care.[21,23,24,26,28,29] Two studies reported repeated nutritional assessments, in addition to standard maternity care, in the control group.[25,27] Of the four nonrandomised studies included, two reported a historical control group[27,28] and two reported concurrent comparison groups.[23,26]

Outcome measures

All studies included reported total GWG. Four studies also reported the proportion of women exceeding IOM recommendations[21,26,28,29] and two studies reported the rate of weight gain, presented in kg per week[27] or kg per trimester.[25]

Reported effects of intervention

Because of the heterogeneity in population characteristics, interventions offered, definitions of outcome measures and durations of intervention, it was not considered appropriate to perform a meta-analysis.

In the studies including women in any weight category or women in the normal and overweight categories, no difference was found between the intervention groups and the control groups in the proportion of women gaining weight within the IOM recommendations[21,25–29] when results for the whole study population were considered, although one study showed an effect in a subgroup of women of normal weight[21] and another found an effect in a subgroup of women of low socio-economic status.[28] One study, however, found a significantly reduced mean GWG in the intervention group, although the rate of adherence to IOM guidelines was not improved.[29]

In three studies of obese women, the interventions were found to be effective compared with standard maternity care in reducing mean GWG[24,29] and in increasing the proportion of women who gained weight within the IOM recommendations.[23] However, in the study by Polley *et al.*,[21] the opposite trend was found in overweight and obese women. In the intervention group with BMI > 26 kg/m^2, the proportion of women gaining weight in excess of the IOM recommendations was increased. Asbee *et al.*,[29] reported no significant difference in adherence to IOM recommendations between obese women receiving an intervention and those not receiving it.

Quality of evidence

Study limitations

Five of eight studies were nonrandomised or quasi-randomised.[23,25–28] In two of the randomised trials, concealment of allocation was not clearly described.[21,24] In five studies there was no blinding,[21,23,27–29], in one study staff at delivery were blinded,[24] in one study women were stated not to have been informed about which study arm they were allocated to,[25] and in one study it was unclear whether participants were informed about this or not.[26] Loss to follow up was >20%, unevenly distributed between intervention and control groups or not stated in six of eight studies.[23–26,28,29] An intention-to-treat analysis was stated to have been carried out in only one study.[21]

Consistency

Inconsistencies were found among the studies in the results obtained for obese woman; there were also inconsistencies among the studies in the differences reported between results for obese women and those for normal/overweight women.

Directness

Two of the studies included only obese women,[23,24] and three focused on particular groups of pregnant women (Cree Indians,[27] African-American teenagers[25] and women with low incomes).[21] As a consequence, the results may not be applicable to the general population of pregnant women.

Precision

It was not possible to extract data from the individual studies to calculate a summary relative risk and a corresponding confidence interval, but the total number of participants was fairly large.

Table 3. Assessment of quality using the GRADE system

No. of studies (no. of participants)	Study limitations	Consistency	Directness	Precision	Publication bias	Quality
8 (1625)	Serious limitations −2	Important inconsistency −1	Indirectness −1	No important imprecision	Unlikely	Very low

Publication bias
Publication bias cannot be completely ruled out, but small negative studies as well as positive studies were identified.

GRADE system
Quality of evidence according to the GRADE system is summarised in Table 3.

As a consequence of important limitations in study design, inconsistency and lack of directness, the overall quality of evidence was judged to be very low using the GRADE system.

Discussion

The increasing prevalence of preconception overweight and obesity in the population of women of reproductive age in the western world is in itself a significant risk factor for adverse maternal and neonatal outcomes. Additional weight gain during pregnancy compounds this risk and also increases the likelihood of high postpartum weight retention. Recommendations regarding adequate weight gain during pregnancy have recently been re-examined by the IOM, and the implementation of these guidelines is a high priority in the western world. Realistic and effective interventions during pregnancy are urgently required.

Despite increasing knowledge of the prevalence of, and risks associated with, high GWG, clinical studies of interventions designed to reduce excessive GWG still appear to be in their infancy. According to predetermined criteria, only eight controlled trials, of which only four were randomised, qualified for inclusion in this review. The studies included were heterogeneous in more than one respect and, as a consequence of limitations in study design, inconsistency and lack of directness, the overall quality of evidence was judged to be very low.

Previously published systematic reviews[19,20] limited inclusion to RCTs only and so did not assess published data from trials with other designs. Because of a lack of RCTs in the field of interest, the inclusion criteria for this review were widened to include all controlled trials. Study design limitations were taken into account in the assessment of the overall quality of evidence. The wide scope of this review might be seen as being inconsistent with our ambition to assess high-quality data, but we believed that it was important to present a complete picture of the current evidence.

This systematic review was limited to the effects of interventions on GWG only. It did not include findings regarding the effects of interventions on postpartum weight retention. Current evidence regarding interventions designed to reduce postpartum weight retention was recently evaluated in a 2007 Cochrane Review.[30]

None of the controlled trials included showed any significant difference between the treatment and control groups with regard to improved adherence to IOM recommendations in women with BMIs in the normal or overweight category, when results for the whole study population were considered. Previous studies showed overweight women to be at high risk for excessive GWG,[31,32] especially when nulliparous.[33,34] Effective interventions in this group would therefore be of great interest. The lack of a significant effect in the studies assessed here may to some extent be explained by their generally small sample sizes.

We found a significant heterogeneity in the mode, intensity, frequency and duration of the interventions carried out. It was, however, the common goal of all the studies to promote behavioural change and give the women an awareness of the impact of body weight on maternal and neonatal health. Differences in the details of the interventions cannot be regarded as a major cause of the differences in the results of the trials included in this review.

Among obese women, there was a significant effect of the intervention in three studies in terms of a reduction in total weight gain.[23,24,29] Limitations in study design and sample size must, however, be considered. Two of the studies had a randomised controlled design but Wolff *et al.* included only 23 and Asbee *et al.* only 12 obese women, in the intervention group. The results of these three studies were not consistent with those of the study by Polley *et al.*,[21] who found that the intervention had the opposite effect in overweight and obese women; that is, women in the intervention group experienced increased weight gain relative to those in the control group. Overall, there is a trend towards positive results in this group of women, but larger randomised trials are needed to provide more evidence.

Total weight gain, rate of weight gain and/or weight gain in excess of IOM recommendations were used as surrogate endpoints in all the trials included. None of the included trials was able to evaluate maternal or neonatal outcome in relation to GWG because of limited sample sizes.

The organisation and standard of maternity care differ between countries and sometimes within countries and even between different parts of cities. An effective intervention to reduce excessive maternal weight gain must not only be based on realistic recommendations but also be feasible for primary healthcare providers to implement. Intensive programmes including regular, one-to-one dietary consultations, sponsored physical activities and/or behavioural intervention therapies are not likely to be an option for all pregnant women in the current healthcare delivery system. Overall, there is a lack of consideration of the cost-effectiveness of interventions in published studies. In future studies, it should also be borne in mind that most maternity-care centres have limited resources. The

development of reliable instruments with which to identify women at high risk of excessive GWG may be a way to focus resources more effectively.

Conclusion

As a consequence of important limitations in study design, inconsistency and lack of directness, the overall quality of evidence was judged to be very low using the GRADE system. The results of published intervention trials are therefore of insufficient quality to enable evidence-based recommendations to be developed for clinical practice in antenatal care.

Disclosure of interests

None.

Contribution to authorship

Both authors planned the study, searched and assessed the literature, and prepared the manuscript.

Details of ethics approval

Ethical approval was not required.

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