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Dietary interventions in overweight and obese pregnant women: a systematic review of the content, delivery, and outcomes of randomized controlled trials

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Dietary interventions in overweight and obese pregnant women : a systematic review of the content, delivery, and outcomes of randomized controlled trials

Dietary interventions in overweight and obese pregnant women: a systematic review of delivery and assessment methodologies in randomised controlled trials

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All authors contributed to writing the paper. SB, LP, KD were responsible for the initial conception and design of the review. AF and KD led on interpretation and analysis. AF and KD were responsible for drafting the initial manuscript. All authors critically reviewed and agreed the final version of the manuscript.

Abstract

Background:

Overweight and obese pregnant women are at risk of complications during pregnancy and in the long term. To date, lifestyle interventions of diet and/or physical activity in these women have had some success in modifying gestational weight gain, but as yet without evidence for substantive influence on clinical outcomes. In the UK, there are currently no dietary guidelines specifically targeting overweight and obese pregnant women, therefore, there is a need to critically examine the methodological design implemented in dietary intervention trials in this high risk group in order to identify components which potentially could translate into clinical practice.

Method:

A structured systematic review following the Preferred Reporting Items for Systematic reviews and Meta-Analyses criteria was conducted. Electronic databases were searched to identify randomised controlled trials on diet and physical activity in overweight and obese pregnant women. Quality assessment and data extraction were performed in duplicate.

Results:

Eleven studies met the inclusion criteria, of which, three were diet only and eight were mixed diet and physical activity interventions. There was significant heterogeneity in the methodological design of the dietary interventions across studies; however, some studies demonstrated that overweight and obese pregnant women showed improved dietary behaviour in response to a lifestyle intervention.

Discussion:

This review reveals that dietary and lifestyle intervention studies, which aim to control gestational weight gain and improve clinical outcomes in overweight and obese pregnant women need clearly defined dietary objectives and reported outcomes to inform the optimal dietary regimen for obese pregnant women in both research and clinical settings.

Introduction

Overweight and obesity, are a major public health concern which contribute significantly to worldwide morbidity, disability, health care expenditures and mortality [1]. The increase in the prevalence of overweight and obesity has resulted in more women being obese at the onset of pregnancy, which is associated with a range of adverse outcomes for both mother and child. Multiple studies have described the risks associated with obesity in pregnancy, which include a heightened risk of gestational diabetes [2], hypertensive disorders including pre-eclampsia [3], failure to progress in labour and higher rates of caesarean section [4, 5]. Overweight and obese pregnant women are also more likely to experience elevated antenatal and postpartum depression symptoms [6]. Infants of obese mothers are at a greater risk of macrosomia [7], stillbirth [8] and congenital malformations [9]. Furthermore, there is evidence to suggest that the effects of maternal obesity may extend beyond pregnancy with studies demonstrating an increased risk of childhood overweight and obesity [10] because of exposure to a suboptimal *in utero* environment [11] .

In the antenatal period, women are in frequent contact with healthcare professionals and may be more motivated to change health behaviours [12]. Many antenatal trials have attempted to restrict gestational weight gain (GWG) and improve clinical outcomes via lifestyle interventions, however, at present, there is inadequate data to support the implementation of any specific approach among overweight and obese pregnant women [13]. There is evidence to suggest that lifestyle interventions are effective in achieving reductions in GWG and reduced risk of adverse outcomes, with diet based interventions being particularly effective [14], however, these studies were not specific to obese women. Previous evidence in overweight and obese pregnant women suggests that whilst a modest reduction in weight gain can be achieved, this was not associated with any significant effect on clinical outcomes including birthweight or macrosomia [15].

Currently, there are no dietary guidelines specifically for overweight or obese pregnant women in the UK. The current strategy follows The National Institute for Health and Clinical Excellence (NICE) guidelines on healthy eating and being physically active [16]. These guidelines include information relating to healthy eating approaches consistent with standard dietary recommendations to the general population and furthermore, advise against energy restriction. The recommendations focus on achieving, and maintaining, a healthy weight during pregnancy by promoting starchy and/or fibre rich foods and consuming at least five portions a day of a variety of fruit and vegetables. Limiting fried, sugar rich and/or high fat foods and drinks is also recommended. In addition, pregnant women are advised to eat breakfast and to monitor meal frequency and portion

sizes [16]. Similarly, in the US, the Institute of Medicine (IOM) recommends that maternal health care advice should focus on healthy dietary choices in order to achieve gestational weight gain goals [17]. Therefore, a need exists to build a consensus in this area in order to develop dietary guidelines for the management of maternal obesity. In order to further this goal, we carried out a comprehensive review of published dietary and lifestyle interventions in order to identify effective approaches, which could be translated into clinical practice. The specific aims of the review were to evaluate: (i) content of dietary interventions; (ii) assessment of dietary intake; (iii) delivery of dietary interventions; and (iv) effects of interventions on dietary behaviour in randomised controlled trials conducted in overweight and obese pregnant women.

Methods

This systematic review was undertaken as part of the International Weight in Pregnancy (iWIP) collaboration, which is examining the differential effects of weight management interventions in various groups by performing an individual patient data (IPD) meta-analysis [18]. The review was also conducted in line with the relevant criteria of the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement [19].

Search strategy

The first step of the IPD meta-analysis included updating the literature search to identify trials published since the completion of the systematic review (HTA No. 09/27/06) on the effects of weight management interventions in pregnancy [20]. Details of the search strategy have been described previously [18]. In brief, relevant studies were searched up to October 2013 using MEDLINE, EMBASE, BIOSIS, LILACS, Pascal, Science Citation Index, Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA). Additional databases searched include Inside Conferences Systems for Information in Grey Literature (SIGLE), dissertation abstracts, and Clinical Trials.gov. Internet searches were also carried out using search engines including OMNI, Google and Copernic. Information on studies in progress, unpublished research, research reported in grey literature and details from commercial providers were additionally sought. Language restrictions were not applied [18].

Inclusion and exclusion criteria

The systematic review inclusion and exclusion criteria were developed using a PICOS structure

(Patient, Intervention, Comparators, Outcome, Study design). Inclusion criteria were: (i) randomised controlled trials which evaluated dietary and lifestyle interventions in pregnancy compared to standard antenatal care; (ii) participants who were overweight (BMI $\geq$ 25 kg/m^2) or obese (BMI $\geq$ 30 kg/m^2); (iii) a defined dietary intervention implemented as part of interventions that were based on diet or a mixed approach comprising diet and physical activity components; (iv) data reporting outcomes for the mother and their infants. Exclusion criteria were: (i) non randomised and observational studies; (ii) participants under the age of 18, multiple pregnancies, participants with a BMI < 25kg/m^2; (iii) studies designed to treat gestational diabetes mellitus (GDM) or which antenatal advice focused solely on physical activity.

Selection of studies and data extraction

Studies identified in the search were assessed for relevance by independent reviewers (KD, AF) based on the information contained in the title and abstracts. For all studies that met the inclusion criteria, the full text articles were retrieved. Disagreement between the two reviewers was resolved through discussion. Study characteristics and findings were extracted in duplicate by reviewers (KD, AF) and entered into standardised tables and checked for completeness and accuracy. In addition, the reviewers attempted to obtain missing information by contacting investigators.

Review of study quality

The methodological quality of each study was assessed by two independent reviewers (AF, ER), using the Cochrane Collaboration tool to assess the risk of bias [21]. Validity characteristics assessed included randomisation method, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias. Inconsistent assessments were discussed and a consensus was reached.

Results

Following an update of the literature search, the number of eligible trials for the IPD meta-analysis is sixty-three. These full-text articles were retrieved for evaluation against the inclusion criteria, eleven of which were included in the review (Fig. 1). Major reasons for exclusion included physical activity only interventions, studies including participants with a BMI < 25kg/m^2, treatment of GDM, adolescent pregnancy, multiple births and articles not published in the English language. The characteristics of the included studies are described in Table 1. Recruitment for the studies occurred between 10 and 28 weeks gestation, however, one study stated that recruitment occurred at the first

antenatal visit, which generally takes place during the first trimester [22]. The total sample size was 3980 participants, which ranged across individual studies from 50 to 2202. The average reported age and pre-pregnancy BMI for the participants in the intervention and control groups was 29.7 years and 34.8 kg/m^2 and 31.1 years and 34.9 kg/m^2, respectively.

The majority of studies aimed to reduce GWG [23-29], three of which had 2 intervention groups [23, 27, 29]. Other study aims included reducing the incidence of GDM [22], improving perinatal outcomes [30], changing dietary and physical activity behaviour [29, 31] and improving maternal and infant health outcomes including large for gestational age (LGA) infants [32]. The duration of the interventions varied from 12-30 weeks. All studies were conducted in developed countries and included; The United States of America [26, 30], Australia [22, 32], Denmark [24, 25, 27], Belgium [23, 29], Italy [28] and the United Kingdom [31]. One study recruited lower socioeconomic participants [22]. Eight studies focused on modifying diet and physical activity [23, 25-29, 31, 32] and three focused on changing diet only [22, 24, 30].

Antenatal care received by the control groups varied, according to country-specific policy; however, in many studies the control group received some standard form of advice on diet and physical activity during pregnancy (Table 2).

Diet Only Intervention

The diet only studies [22, 24, 30] used a variety of strategies to modify dietary intake (Table 2). These included incorporating a multidisciplinary approach, providing individualised feedback on diet and suggesting healthier choices to participants [22], the use of a nutritional regimen which followed guidelines for the treatment of GDM [30] and providing dietary counselling based on Danish recommendations for eating a healthy diet [24]. Two of the studies aimed to reduce energy intake [24, 30]. All studies recorded the method used to assess dietary intake of the participants, which included three 7-day weighted food records [24], an audit of items consumed in the day before antenatal visits [22] and a diary notebook with daily food and beverage consumption [30]. One study provided information on the dietary analysis methods [24].

To deliver the intervention, two studies enlisted the input of a dietitian [24, 30] and one study used a food technologist [22] (Table 3). The frequency and intensity of the dietary interventions varied from a five minute intervention at each antenatal visit [22] to ten, one hour consultations [24]. The sessions occurred at antenatal visits and consultations; therefore, it is assumed that the delivery of the intervention was face to face.

No studies demonstrated a significant difference in infant birthweight but all reported a significant difference in GWG between the intervention and control groups (Table 4). In addition, two studies reported an improvement in dietary intake in the intervention group. Quinlivan *et al.* 2011 reported an increase in the consumption of water, fresh fruit, vegetables and home-cooked meals and a reduction in carbonated 'fizzy' drinks, juices and fast foods [22]. Wolff *et al.* 2008 reported a significant reduction of fat, energy and carbohydrate and an increase in protein intake in the intervention group.

Combined diet and physical activity intervention

Eight studies focused on changing both dietary intake and physical activity [23, 25-29, 31, 32]. Similar to the diet only studies, the combined intervention trials aimed to modify behaviour using a variety of approaches (Table 2). Five studies followed country specific guidelines [23, 25, 27, 29, 32], one study focused on implementation of the dietary approaches to stop hypertension (DASH) diet [26] and two studies aimed to reduce the consumption of high glycaemic index (GI) foods and substitute for healthier alternatives [28, 31]. All studies specified the dietary assessment method, which included 7-day food diaries in each trimester [23, 29], food frequency questionnaires (FFQs) at various time points throughout gestation [26-28, 32], repeated 24hr recalls [31] and a Danish questionnaire [25]. Five of the studies reported on the process used to analyse the dietary intake data [26, 28, 29, 31, 32].

In five studies, a dietitian delivered an aspect of the intervention [25-28, 32], one used a midwife to deliver advice [23], one included nutritionist- delivered advice [29], and one used a health trainer [31] (Table 3). The interventions included individual and group based sessions which ranged in frequency from two to sixteen contacts [26]. Five studies specified the time for each session, which varied from 30 minutes [25] to 2 hours [23].

Five studies reported a significant decrease in GWG for overweight or obese participants in the intervention group [23, 25-28] and three studies found no difference in weight gain [29, 31, 32] (Table 4). Two studies reported a significant difference in birthweight. Petrella *et al.* 2013 and Vinter *et al.* 2011 reported that the intervention groups had higher birthweights; however, the authors provided an explanation for this result. Only four studies reported on the positive effect the intervention had on the overall diet, including for example, a significant increase in fruit and vegetable intake [28, 29, 32]. A significant decrease in saturated fat intake was reported by three studies [29, 31, 32] and a reduction in glycaemic load (GL) in one study [31]. Vinter *et al.* 2011 reported on the improvement of eating habits including healthy eating or traditional eating patterns from baseline to 35 weeks gestation.

The overall quality of the included studies was varied (Supplementary information Fig. 1). All studies reported confirmation of adequate sequence generation. There was no evidence of a high risk of bias for allocation concealment and blinding, however, a large proportion of the studies were unclear in their reporting in these domains.

Discussion

This systematic review critically examined the design of reported dietary interventions, which aimed to control GWG and to improve clinical outcomes in overweight and obese pregnant women. Eleven randomised controlled trials were included in the review, three of which focused solely on diet and a further eight, which, comprised both diet and physical activity components. The outcome of this study highlights considerable variation in the types of dietary interventions and our conclusions are consistent with previously reported systematic reviews [14, 15, 33].

Content

In the eligible studies examined, a wide and heterogeneous range of dietary advice was provided to participants. The majority of studies provided healthy eating advice based on national recommendations or nutrition guidelines [23-25, 27, 29, 32]. As national guidelines for dietary interventions are country specific, it is somewhat difficult to directly compare studies in this regard. In general, the dietary information provided to participants focused on increasing the intake of foods know to be beneficial to general health such fruit, vegetables and wholegrains, while decreasing the intake of refined carbohydrates and foods high in fat, including saturated fat and sugar.

One dietary intervention was based on more precise guidelines for example, the nutrition programme pursued by Thornton *et al.* 2009 followed dietary guidelines similar to those used in patients with the diagnosis of GDM. Other studies utilised a more specific dietary approach, for example, focusing on decreasing dietary GL in order to improve pregnancy outcomes by reducing postprandial increments in maternal glucose concentrations [31]. Two studies provided advice to follow a particular eating pattern such as DASH [26] or a Mediterranean style diet [27]. The DASH diet has been shown to lower blood pressure, lipids, and fasting glucose [34], while the Mediterranean diet is associated with a low prevalence of major diseases such as cardiovascular disease [35].

Macronutrient and energy composition of the intervention diets varied considerably across studies. Specific intake of macronutrients ranged from 40-55% for carbohydrates, 9-30% for protein, 25-35% for total fat and 6%-10% for saturated fat. Several studies [24, 26-28, 30] provided specific energy intake targets, while energy intake was not restricted in two studies [29, 31].

These results highlight the diverse approaches utilised to modify dietary behaviour in antenatal diet and lifestyle interventions. In many studies, however, there was a lack of descriptive information on the dietary content of the intervention in addition to disparities in the care received by the control groups, many of who received some form of dietary advice. An inevitable limitation in dietary interventions is the lack of blinding, which may result in the control group modifying their dietary intake, which may have an impact on dietary and pregnancy outcomes.

Assessment

The majority of studies considered for this review aimed to modify diet to limit GWG as the primary outcome. Accurate estimation of dietary intake is essential in order to assess adherence to a dietary regime and to examine the relationship between diet and pregnancy outcomes. All authors described the method(s) used to assess dietary intake of the participants, although, in general, the methods used to evaluate the nutritional composition of the diets were poorly described. There was considerable variation in selection of dietary assessment tools across studies. Several studies [23, 24, 29] used prospective dietary assessment methods such as food records/diaries, one of which was weighed [24]. Retrospective assessment methods included FFQs [26-28, 32] and repeated 24-hour recalls [31]. Other assessment methods included a country specific questionnaire [25], audit of items [22] or a diary notebook [30].

It is widely reported that dietary intake is challenging to measure accurately and selection of the assessment instrument relies on considering a variety of factors including the research objective, study design and available resources. FFQs are designed to assess habitual diet over a reference period and two well-known FFQs, the Harvard or Willett questionnaire [36] and the Block questionnaire [37], respectively, were employed by two studies [26, 32]. The effective use of FFQs are limited by the number of listed food items and most often, do not record detailed portion size information, which may profoundly impact on accurate reporting of dietary intake . The number of food items assessed by the FFQs in the review ranged from 126 [32] to 360 [27]. Weighed or estimated food diaries/records and 24-hour recalls provide more detailed data on food and nutrient intakes, however, the length of collection can impact the validity of the data obtained and are more labour intensive to administer and analyse. The number of food record collection days was

consistent across studies at seven [23, 24, 29]. Under-reporting has been documented across dietary assessment methods [38] but has been found to be particularly prevalent in obese and pregnant women [39, 40]. The limitations of subjective assessment methods can be overcome by incorporating biomarkers into the study design, which future antenatal studies assessing dietary intake should consider.

Delivery

Dietary advice was routinely provided by more than one individual, with varying background training, across studies. Dietitians were used most frequently [24-28, 30, 32], in addition to a nutritionist [29], midwife [23], research assistants [32], health trainers [31], interventionist [26] and food technologist [22]. In terms of implementation of an intervention into clinical practice, the individual delivering the intervention must be considered carefully. This inconsistency in the training of those providing dietary advice makes it difficult to directly compare across studies. The majority of interventions involved face-to-face sessions and several studies used telephone contacts to reinforce the information which may facilitate behaviour change. The interventions were delivered individually or in a group setting or both. Group sessions may be may be less cost and time intensive, however, the evidence for this approach as an effective alternative is varied [41].

There was considerable variation in the intensity of interventions provided across the studies, which has been previously reported in the literature [14, 15, 33]. Frequency ranged from a single counselling session, to ten one hour consultations with a dietitian [24]. The intensity of an intervention may have an effect on outcomes, particularly in high-risk groups such as overweight and obese pregnant women; however, the feasibility of implementing an intense intervention into clinical practice needs to be considered within each health care system.

Compliance was poorly reported across studies and this observation is consistent with previously reported studies [14, 15, 33] with only a small proportion of studies reporting attendance rates. Compliance is a significant issue when considering the effect on pregnancy outcomes, in addition to providing information, which could potentially facilitate or hinder implementation of an intervention into daily practice.

Outcomes

Eight studies, three diet-only [22, 24, 30], and five mixed interventions [23, 25-28], were effective in limiting GWG in overweight and obese pregnant women. These interventions incorporated various types of dietary guidance but were either relatively intense with a high frequency of interaction or

incorporated daily self monitoring of dietary intake [30]. No studies reported a significant reduction in birthweight.

It is clear that the efficacy of interventions in changing dietary behaviour is poorly reported (Table 4) and consequently, the effect of diet on GWG and birthweight is difficult to establish. Several studies reported improvements in maternal diet following the intervention. The intervention group in the study reported by Dodd *et al.* 2014 improved their nutrient intake, food groups and healthy eating score. Guelinckx *et al.* 2010 found a significant decrease in total and saturated fat and Poston *et al.* 2013 showed a significant decrease in GL and saturated fat intake in the intervention group. These studies did not reduce GWG, although the pilot study in Poston *et al.* 2013 was not powered to look at GWG or clinical outcomes. In contrast, three studies [22, 24, 28] reported improvements in diet and lower GWG. These results suggest that overweight and obese pregnant women are amenable to changing their diet in response to an intervention; however, this does not always result in changes to GWG or clinical outcomes.

The effect of a dietary intervention on pregnancy outcomes is further dependent on the duration of the intervention. Recruitment gestational age ranged from week 10 to 28, therefore the timing of initiation may influence the ability of a dietary intervention to change diet or improve pregnancy outcomes.

This systematic review has notable strengths; these include a comprehensive search strategy, the use of independent reviewers to carry out identification of relevant studies and compliance with the PRISMA statement. However, the review was limited by the heterogeneous nature of the studies investigated as there was considerable variation in the methods employed by the dietary interventions included, therefore meta-analyses could not be performed. Furthermore, the majority of the studies focused on White participants, which may not be generalisable to other ethnic groups. In addition the possibility of publication bias should to be considered, as those studies not published in the English language were not included.

Recommendations for further research

There is need for further well-designed dietary interventions as part of large-scale randomised controlled trials to examine the effects of diet on GWG and clinical outcomes in overweight and obese pregnant women. Several limitations were identified in the reporting of aspects of the intervention. There was a paucity of descriptive information on the provision of specific dietary goals, use and analysis of dietary assessment instruments, intensity of interventions, patient

compliance and dietary outcomes. We recommend that future studies incorporate more detailed information regarding the dietary component of an intervention, in addition to a more complete description of specific details relating to implementation and adequate completion. Studies should focus on including robust dietary assessment methods to assess adherence to a dietary intervention. In addition, dietary outcomes, and how they affect GWG and clinical outcomes should be reported in future studies.

Conclusion

This systematic review has found that dietary and lifestyle interventions in overweight and obese pregnant women can lead to reductions in GWG and an improvement in dietary behaviour, however, without an effect on clinical outcomes. Currently, no recommendations exist for the most effective diet to control weight gain and to improve clinical outcomes in overweight and obese women. The results from this systematic review highlight the major differences in the methodological design of dietary interventions in this high risk group. Until such time that sufficiently large randomised controlled trials with defined dietary objectives and assessment methods have been performed in this group, there remains no evidence-based approach for any specific dietary regimen to improve pregnancy outcomes in overweight and obese women.

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