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

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100 **Key words:** maternal obesity, dietary assessment, antenatal intervention

101

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

106

107 **Abstract**

108 **Background:**

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

116 **Method:**

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

121 **Results:**

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

127 **Discussion:**

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

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136 **Introduction**

137 Overweight and obesity, are a major public health concern which contribute significantly to
138 worldwide morbidity, disability, health care expenditures and mortality ^[1]. The increase in the
139 prevalence of overweight and obesity has resulted in more women being obese at the onset of
140 pregnancy, which is associated with a range of adverse outcomes for both mother and child.
141 Multiple studies have described the risks associated with obesity in pregnancy, which include a
142 heightened risk of gestational diabetes ^[2], hypertensive disorders including pre-eclampsia ^[3], failure
143 to progress in labour and higher rates of caesarean section ^[4, 5]. Overweight and obese pregnant
144 women are also more likely to experience elevated antenatal and postpartum depression symptoms
145 ^[6]. Infants of obese mothers are at a greater risk of macrosomia ^[7], stillbirth ^[8] and congenital
146 malformations ^[9]. Furthermore, there is evidence to suggest that the effects of maternal obesity may
147 extend beyond pregnancy with studies demonstrating an increased risk of childhood overweight and
148 obesity ^[10] because of exposure to a suboptimal *in utero* environment ^[11] .

149
150 In the antenatal period, women are in frequent contact with healthcare professionals and may be
151 more motivated to change health behaviours ^[12]. Many antenatal trials have attempted to restrict
152 gestational weight gain (GWG) and improve clinical outcomes via lifestyle interventions, however,
153 at present, there is inadequate data to support the implementation of any specific approach among
154 overweight and obese pregnant women ^[13]. There is evidence to suggest that lifestyle interventions
155 are effective in achieving reductions in GWG and reduced risk of adverse outcomes, with diet based
156 interventions being particularly effective ^[14], however, these studies were not specific to obese
157 women. Previous evidence in overweight and obese pregnant women suggests that whilst a modest
158 reduction in weight gain can be achieved, this was not associated with any significant effect on
159 clinical outcomes including birthweight or macrosomia ^[15].

160
161 Currently, there are no dietary guidelines specifically for overweight or obese pregnant women in
162 the UK. The current strategy follows The National Institute for Health and Clinical Excellence
163 (NICE) guidelines on healthy eating and being physically active ^[16]. These guidelines include
164 information relating to healthy eating approaches consistent with standard dietary recommendations
165 to the general population and furthermore, advise against energy restriction. The recommendations
166 focus on achieving, and maintaining, a healthy weight during pregnancy by promoting starchy
167 and/or fibre rich foods and consuming at least five portions a day of a variety of fruit and
168 vegetables. Limiting fried, sugar rich and/or high fat foods and drinks is also recommended. In
169 addition, pregnant women are advised to eat breakfast and to monitor meal frequency and portion

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

179

180 **Methods**

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

186 **Search strategy**

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

199 **Inclusion and exclusion criteria**

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

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

210

211 **Selection of studies and data extraction**

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

218

219 **Review of study quality**

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

225

226 **Results**

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

234 antenatal visit, which generally takes place during the first trimester ^[22]. The total sample size was
235 3980 participants, which ranged across individual studies from 50 to 2202. The average reported
236 age and pre-pregnancy BMI for the participants in the intervention and control groups was 29.7
237 years and 34.8 kg/m² and 31.1 years and 34.9 kg/m², respectively.

238 The majority of studies aimed to reduce GWG ^[23-29], three of which had 2 intervention groups ^{[23, 27,}
239 ^{29]}. Other study aims included reducing the incidence of GDM ^[22], improving perinatal outcomes
240 ^[30], changing dietary and physical activity behaviour ^[29, 31] and improving maternal and infant
241 health outcomes including large for gestational age (LGA) infants ^[32]. The duration of the
242 interventions varied from 12-30 weeks. All studies were conducted in developed countries and
243 included; The United States of America ^[26, 30], Australia ^[22, 32], Denmark ^[24, 25, 27], Belgium ^[23, 29],
244 Italy ^[28] and the United Kingdom ^[31]. One study recruited lower socioeconomic participants ^[22].
245 Eight studies focused on modifying diet and physical activity ^[23, 25-29, 31, 32] and three focused on
246 changing diet only ^[22, 24, 30].

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

250 **Diet Only Intervention**

251 The diet only studies ^[22, 24, 30] used a variety of strategies to modify dietary intake (Table 2). These
252 included incorporating a multidisciplinary approach, providing individualised feedback on diet and
253 suggesting healthier choices to participants ^[22], the use of a nutritional regimen which followed
254 guidelines for the treatment of GDM ^[30] and providing dietary counselling based on Danish
255 recommendations for eating a healthy diet ^[24]. Two of the studies aimed to reduce energy intake ^{[24,}
256 ^{30]}. All studies recorded the method used to assess dietary intake of the participants, which included
257 three 7-day weighted food records ^[24], an audit of items consumed in the day before antenatal visits
258 ^[22] and a diary notebook with daily food and beverage consumption ^[30]. One study provided
259 information on the dietary analysis methods ^[24].

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

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

272 **Combined diet and physical activity intervention**

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

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

287 Five studies reported a significant decrease in GWG for overweight or obese participants in the
288 intervention group ^[23, 25-28] and three studies found no difference in weight gain ^[29, 31, 32] (Table 4).
289 Two studies reported a significant difference in birthweight. Petrella *et al.* 2013 and Vinter *et al.*
290 2011 reported that the intervention groups had higher birthweights; however, the authors provided
291 an explanation for this result. Only four studies reported on the positive effect the intervention had
292 on the overall diet, including for example, a significant increase in fruit and vegetable intake ^{[28, 29,}
293 ^{32]}. A significant decrease in saturated fat intake was reported by three studies ^[29, 31, 32] and a
294 reduction in glycaemic load (GL) in one study ^[31]. Vinter *et al.* 2011 reported on the improvement
295 of eating habits including healthy eating or traditional eating patterns from baseline to 35 weeks
296 gestation.

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

301

302 **Discussion**

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

309 **Content**

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

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

327 Macronutrient and energy composition of the intervention diets varied considerably across studies.
328 Specific intake of macronutrients ranged from 40-55% for carbohydrates, 9-30% for protein, 25-
329 35% for total fat and 6%-10% for saturated fat. Several studies ^[24, 26-28, 30] provided specific energy
330 intake targets, while energy intake was not restricted in two studies ^[29, 31].

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

337 **Assessment**

338 The majority of studies considered for this review aimed to modify diet to limit GWG as the
339 primary outcome. Accurate estimation of dietary intake is essential in order to assess adherence to a
340 dietary regime and to examine the relationship between diet and pregnancy outcomes. All authors
341 described the method(s) used to assess dietary intake of the participants, although, in general, the
342 methods used to evaluate the nutritional composition of the diets were poorly described. There was
343 considerable variation in selection of dietary assessment tools across studies. Several studies ^{[23, 24,}
344 ^{29]} used prospective dietary assessment methods such as food records/diaries, one of which was
345 weighed ^[24]. Retrospective assessment methods included FFQs ^[26-28, 32] and repeated 24-hour recalls
346 ^[31]. Other assessment methods included a country specific questionnaire ^[25], audit of items ^[22] or a
347 diary notebook ^[30].

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

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

364 **Delivery**

365 Dietary advice was routinely provided by more than one individual, with varying background
366 training, across studies. Dietitians were used most frequently [24-28, 30, 32], in addition to a nutritionist
367 [29], midwife [23], research assistants [32], health trainers [31], interventionist [26] and food technologist
368 [22]. In terms of implementation of an intervention into clinical practice, the individual delivering the
369 intervention must be considered carefully. This inconsistency in the training of those providing
370 dietary advice makes it difficult to directly compare across studies. The majority of interventions
371 involved face-to-face sessions and several studies used telephone contacts to reinforce the
372 information which may facilitate behaviour change. The interventions were delivered individually
373 or in a group setting or both. Group sessions may be less cost and time intensive, however,
374 the evidence for this approach as an effective alternative is varied [41].

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

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

386 **Outcomes**

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

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

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

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

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

415 **Recommendations for further research**

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

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

427 **Conclusion**

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

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