Use of dietary assessment tools in randomized trials evaluating diet-based interventions in pregnancy: a systematic review of literature

Bassel H. Al Wattar, Bronacha Mylrea-Lowndes, Catrin Morgan, Amanda P. Moore, and Shakila Thangaratinam

Purpose of review
Accurate assessment of dietary intake in interventional trials is the key to evaluate changes in dietary behaviour and compliance. We evaluated the use of dietary assessment tools in randomized trials on diet-based interventions in pregnancy by a systematic review.

Recent findings
We updated our previous search (until January 2012) on trials of diet and lifestyle interventions in pregnancy using Medline and EMBASE up to December 2015. Two independent reviewers undertook study selection and data extraction. We assessed the characteristics of dietary assessment tools, the timing and frequency of use and any validation undertaken.

Two-thirds (39/58, 67%) of the included studies used some form of tools to assess dietary intake. Multiple days’ food diaries were the most commonly used (23/39, 59%). Three studies (3/39, 8%) validated the used tools in a pregnant population. Three studies (3/39, 8%) prespecified the criteria for adherence to the intervention. The use of dietary assessment tools was not associated with study quality, year of publication, journal impact factor, type of journal and the study sample size.

Summary
Although self-reporting dietary assessment tools are widely used in interventional dietary trials in pregnancy, the quality and applicability of existing tools are low.

Keywords
assessment, diet, intervention, pregnancy, systematic review

INTRODUCTION
Maternal nutritional status before and during the pregnancy has a significant influence on pregnancy-related outcomes [1]. Diet and lifestyle interventions in pregnancy reduce gestational weight gain and have the potential to improve other outcomes such as gestational diabetes, preeclampsia and preterm delivery [2,3*].

Dietary interventional trials use a variety of tools to evaluate participants’ habitual dietary pattern, the effect of the intervention on dietary intake and participants’ compliance with the intervention. Such tools have to be reliable, accurate and valid to improve the interpretation of the study findings [4]. Clinical trials in nonpregnant population traditionally use dietary histories as a gold standard to capture participants’ dietary intake [4]. This is often time and cost consuming in large trial settings mandating the use of other short-term tools such as short food diaries and food frequency questionnaires (FFQs) [5–7].

Pregnancy poses unique challenges for reliable assessment of dietary intake, due to its physiological changes, pregnancy-related conditions such as excessive vomiting and variation in energy requirement per trimester [8]. These changes can significantly reduce the reliability of dietary assessment in...
pregnancy and increase the risk of bias in the trial’s findings [9]. We undertook a systematic review to assess the characteristics and quality of dietary assessment tools used in randomized trials on pregnant women and the factors associated with their use.

METHODS

Literature search and study identification
We updated our previously published search for randomized studies on diet and lifestyle interventions in pregnancy (January 2012) using Medline and EMBASE until December 2015 to identify any new studies. The search strategy was designed in a multistep process by combining search terms related to pregnancy and diet [2]. There were no language restrictions (Appendix 1, http://links.lww.com/COOG/A33).

Study selection
We included all randomized trials of dietary interventions in a pregnant population. We obtained details of the dietary assessment tool and the outcomes measures. Two independent reviewers (B.H.A.W. and B.M.L.) performed the study selection process in two stages. First, we screened the full titles and abstracts of all identified citations related to pregnancy and diet [2]. There were no language restrictions (Appendix 1, http://links.lww.com/COOG/A33).

Quality assessment of included studies
We assessed the quality of included randomized studies using the Jadad score [10]. One point was awarded for each of the following: study described as randomized, the randomization method was appropriate; the study was described as double blinded, the allocation method was appropriate; withdrawals and dropouts were described. Studies with a score above 3 were considered to be of high quality. A score of 3 was considered to be of moderate quality and studies with a score of 2 or less were considered to be of low quality.

Data extraction and analysis
Two independent reviewers extracted data using predesigned data extraction forms (C.M. and B.M.L.). We collected data on details such as the study design, country of study, journal impact factor, study population characteristics, type of dietary intervention evaluated and the outcomes. We recorded the type of dietary assessment tools used, time and frequency of use in pregnancy, and whether the authors evaluated the validity and reliability of the tool in the study population. Journals with an impact factor of more than 10 were considered to be of high impact.

We used logistic regression modelling to assess the effect of study quality, year of publication, journal impact factor, journal type (general vs. specialist) and study sample size on the probability of using dietary assessment tools in clinical trials. Statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp, Armonk, New York, USA) and Microsoft Excel (Office 2010; Microsoft, Chicago, Illinois, USA).

RESULTS

From 19,563 potentially relevant citations, 58 randomized trials assessed dietary intervention. Of these, only 39 studies used a dietary assessment tool and were included in our review. Figure 1 shows the details of the study selection process.

Characteristics of the studies using dietary assessment tools
Overall, 9,728 pregnant women were included in 39 studies. Five studies targeted pregnant women with a BMI at least 30 (5/39, 13%), and 21 included pregnant women with any BMI (21/39, 54%). Three studies recruited women at high risk for gestational diabetes (3/39, 8%), and 10 evaluated the effect of diet on women with gestational diabetes (10/39,
The intervention consisted solely of dietary counselling in 30/39 (77%) studies and a combination of dietary and physical activity advice in 9/39 (23%) studies. The majority of studies introduced the dietary intervention by the end of the second trimester (35/39, 90%).

Most studies were conducted in the United States of America (10/39, 27%), followed by Australia (6/39, 15%). Five studies (5/39, 13%) were published in general medical journals and the rest in specialist journals. Only two were published in high impact factor journals (impact factor >10). Table 1 provides a brief summary of the characteristics of the included studies.

Characteristics of dietary assessment tools

Short-term food diaries were most commonly used to assess dietary intake in trials (23/39, 59%), followed by FFQs (12/39, 31%) and 24-h recalls (8/39, 20%). Four studies used two assessment tools jointly [11–14]. The types of food diaries varied in duration: 3-day (13/23, 57%), 4-day (1/23, 4%), 5-day (1/23, 4%) and 7-day diaries (8/23, 35%). Only two studies used weighted food diaries [11,15]. FFQs varied in the number of items included from 13 to 181.

Three studies validated the dietary assessment tools used in the study population [13,23,24]. Of these, two (2/39, 5%) developed and validated the FFQ in the study population using nonweighted 5-day food diaries [24] and 24-h recall [13]. One study validated the content of the 24-h recall via a panel of experts [23]. Four trials (4/39, 10%) defined criteria for adherence to the dietary intervention [24,25,26,27]. Three studies used biomarkers to assess the effectiveness of the intervention [11,15,19], and one used biomarkers to assess adherence to the intervention and change in dietary intake [22] (Table 1).

Quality assessment of studies using dietary assessment tools

The use of dietary assessment tools in trials was not associated with study quality ($P = 0.10$), year of publication (before or after 2005) ($P = 0.88$), journal impact factor ($P = 0.48$), type of journal (general vs. specialist) ($P = 0.33$) or the study sample size ($P = 0.19$).

DISCUSSION

Our review summarizes the use and quality of dietary assessment tools in randomized trials on dietary interventions in a pregnant population. Less than two-thirds of interventional studies included such an assessment tool. This practice did not seem to correlate with the study quality, publication journal or study sample. Self-reporting tools (SRTs) were the most commonly used, consistent with interventional dietary studies outside pregnancy [28].

Strengths and limitations

We performed a comprehensive review of the methods used to assess dietary changes in pregnancy. The trials were identified by a systematic review using a sound methodology, with no search
| Author and year | Country of study | Journal | Characteristics of intervention | GA at intervention | Dietary intervention | Diet assessment tool |
|----------------|------------------|---------|--------------------------------|-------------------|---------------------|---------------------|
| Asemi et al. (2014) | Iran | European Journal of Clinical Nutrition | Primigravida, age 18–40, diagnosed with GDM at 24–28 week gestation | Any 24–28 weeks | DASH diet was rich in fruits, vegetables, low-fat dairy products, low in saturated fats and cholesterol, refined grains and sweets | Weekly 2-day dietary recall and one weekend day |
| Bechtel-Blackwell et al. (2002) | USA | Clinical Nursing Research | African American primagravidas, age 13–18 | Any First trimester to early second trimester | Nutritional education | CAPI (24 h dietary recall + general nutrition questions) |
| Bo et al. (2014) | Italy | Diabetes, Obesity and Metabolism | Age 18–50; GDM diagnosis, singleton pregnancy | <40 24–26 weeks | Individually prescribed diet + physical activity | FFQ |
| Bosaeus et al. (2015) | Sweden | Nutritional Journal | Age 20–45, European descent, nondiabetic, no neuroleptic drugs, and vegetarianism or veganism | 18.5–24.9 12–18 weeks | Individualized dietary counselling | FFQ |
| Briley et al. (2002) | USA | Journal of The American Dietetic Association | African American with no preexisting health conditions or diet | Any <24 weeks | In-home, prenatal nutritional advice | 24 h recalls |
| Ferrara et al. (2011) | USA | Diabetes Care | Singleton pregnancy with gestational diabetes, age >18, English speaking | Any After diagnosis of GDM | DEBI for women with gestational diabetes | 7 days dietary diaries |
| Grant et al. (2011) | Canada | Diabetes Research and Clinical Practice | Age 18–45, diagnosed with GDM or IGT, no chronic illness affecting carbohydrate metabolism; No type 1 or type 2 diabetes; not using insulin before providing consent | Any <34 weeks | Dietary counselling on nonstarchy food | 7 days dietary diary |
| Grant et al. (2011) | Canada | Diabetes Research and Clinical Practice | Singleton pregnancy, age 18–45, diagnosed with GDM | Any 28 weeks | Patients introduced to diabetes food guide and current Canadian dietary recommendations | 3 days diary + FFQ |
| Guelinckx et al. (2010) | Belgium | The American Journal of Clinical Nutrition | Obese white primigravidas <15 | Any >29 | Nutritional advice from a brochure/lifestyle education by a nutritionist | 7 days dietary diary |
| Hawkins et al. (2015) | USA | Diabetic Medicine | Hispanic women age 18–40, no history of type 2 diabetes, hypertension, heart disease or chronic renal disease; no current medications adversely influence glucose metabolism | Any <18 weeks | In-person behavioural counselling from trained research assistants | 2 h recalls |
| Hui et al. (2011) | Canada | British Journal of Obstetrics and Gynaecology | Nondiabetic urban-living pregnant women <26 weeks gestation | Any 26 weeks | Community-based group exercise sessions, home exercise and dietary counselling | 3 days dietary diary |
| Author and year             | Country of study | Journal                        | Characteristics of intervention population                                                                 | BMI | GA at intervention | Dietary intervention                                                                 | Diet assessment tool               |
|-----------------------------|------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------|-----|---------------------|---------------------------------------------------------------------------------------|-----------------------------------|
| Ilmonen et al. (2011)       | Finland          | Clinical Nutrition            | Pregnant women less than 17 weeks gestation and no metabolic diseases                                       | Any | <17 weeks           | Dietary counselling with probiotics or placebo                                         | 3 days food diary                 |
| Jackson et al. (2010)       | USA              | Patient Education and Counselling | English speaking, ≥18 years, <26 weeks gestation                                                              | Any | 26 weeks           | Teaching and counselling session about nutrition, exercise and weight gain using the [Video Doctor](#) | FFQ (18 items)                    |
| Jeffries et al. (2009)      | Australia        | Medical Journal of Australia  | English speaking, ≤14 weeks gestation, age 18-45 years                                                     | Any | 14 weeks           | Nutritional advice                                                                     | Eating habit questionnaire (used to distract from aim of project) |
| Jelsma et al. (2013)        | Netherlands      | BMC Pregnancy & Childbirth    | Pregnant women at risk of GDM < 19 + 6 weeks. Singleton pregnancy, age <18 years                             | >29 | <19 weeks + 6 days  | Five individual sessions and 4 optional telephone calls with lifestyle coach. Daily intake of vitamin D | 3 days food diary + FFQ (12 items) |
| Khoury et al. (2005)        | Norway           | American Journal of Obstetrics and Gynecology | Singleton pregnancy, nonsmoking, white ethnicity, age 21–38                                                | Any | 19–32               | Nutritional advice, low cholesterol diet and supplement intake in pregnancy            | 7 days weighed dietary diary      |
| Kiefferv et al. (2014)      | USA              | American Journal of Public Health | Hispanic pregnant women, age <18 years, resident in southwest Detroit, <20 weeks gestation                  | Any | <20 weeks           | Healthy Mothers on the Move dietary program implemented in 2 home visits and 9 group meetings over 11 weeks | FFQ                               |
| Korpi-Hyovalti et al. (2012)| Finland          | The British Journal of Nutrition | Pregnant women at high risk of gestational diabetes                                                          | Any | 12 weeks           | Dietary and lifestyle advice                                                            | 4 days food diary                 |
| Luoto et al. (2011)         | Finland          | PLOS Medicine                | Pregnant euglycaemic women, 8–12 weeks gestation, at least one risk factor for GDM                           | Any | 8–12 weeks          | Individual intensified counselling on physical activity, diet and weight gain          | FFQ (181 items)                   |
| Man Shek et al. (2014)      | China            | Arch Gynecol Obstet          | Chinese, residents in Hong Kong, age ≥18, diagnosed with IGT but otherwise in general good health, understand Chinese language  | Any | 28–30 weeks       | Dietary advice, individual optimal caloric intake measured, individual counselling by a registered dietician | 5 days food diary                 |
| Moreno-Castilla et al. (2013)| Spain            | Diabetes Care                | Age 18–45, singleton pregnancy, diagnosis of GDM <35 weeks                                                | Any | <35 weeks           | Individualized dietary advice                                                          | 3 days food diary                 |
| Moses et al. (2009)         | Australia        | Diabetes Care                | Age 18–45, singleton pregnancy, no previous GDM, nonsmoker, diagnosis of GDM                               | Any | 28–32 weeks       | Individualized dietary advice                                                          | 3 days food diary                 |
| Moses et al. (2009)         | Australia        | American Journal of Nutrition | ≤20 weeks gestation, singleton pregnancy, age >18, ability to read and understand English                  | Any | 20 weeks           | Detailed dietary education tailored for the assigned diet                             | 3 days food diary                 |
| Moses et al. (2014)         | Australia        | The American Journal of Clinical Nutrition | ≤20 weeks gestation, singleton pregnancy, 18 years or older, read and understand English                   | Any | <20 weeks           | Detailed dietary education tailored for assigned diet and individual requirements for pregnancy | 3 days food diary                 |
| Petrella et al. (2013)      | Italy            | Journal of Maternal-Fetal & Neonatal Medicine | Age ≥18 years, singleton pregnancy                                                                  | ≥25 | 12 weeks           | TLC Program                                                                            | FFQ (158 items)                   |
| Author and year | Country of study | Journal | Characteristics of intervention population | BMI | GA at intervention | Dietary intervention | Diet assessment tool |
|-----------------|------------------|---------|---------------------------------------------|-----|---------------------|---------------------|---------------------|
| Polley et al. (2002) | USA | International Journal of Obesity | Age >18 years, singleton pregnancy, gestation <20 weeks | ≥19.8 | 20 weeks | Education about weight gain, healthy eating, and exercise | Short FFQ (13 items) |
| Poston et al. (2013) | UK | BMC Pregnancy & Childbirth | Obese, singleton pregnancy, gestation 15–18 weeks | ≥30 | 15–18 weeks | One-to-one and group sessions with health trainer providing dietary and physical activity advice | 24 h recalls + short FFQ |
| Quinlivan et al. (2011) | Australia | Australian and New Zealand Journal of Obstetrics and Gynaecology | Singleton pregnancies, obese or overweight, English speaking | ≥25 | Not reported | Dietary advice and clinical psychology | 24 h itemized food consumption recalls |
| Rae et al. (2000) | Australia | Australian and New Zealand Journal of Obstetrics and Gynaecology | Pregnant women with GDM | >110% of ideal body weight | <28 +1 weeks | Nutritional advice on a moderately energy restricted diabetic diet | 3 days food diary |
| Rauh et al. (2013) | Germany | BMC Pregnancy & Childbirth | Age >18 years, singleton pregnancy, <18 weeks gestation with sufficient German language skills | ≥18.5 | 18 weeks | Advice on healthy lifestyle, diet and physical activity with individualized goals | 7 days dietary diary |
| Rhodes et al. (2010) | USA | American Journal of Nutrition | BMI 25–45, age ≥25, singleton pregnancy. | 25–45 | 13–28 weeks | Nutritional education, dietary counselling and food provision | 24 h recalls |
| Rönnö et al. (2014) | Finland | BMC Pregnancy & Childbirth | History of GDM/BMI ≥30, <20 weeks | ≥30 | 20 weeks | Lifestyle counselling encouraging healthy diet and physical activity | 3 day food diary |
| Sagedal et al. (2013) | Norway | BMC Public Health | Singleton pregnancy, >18 years old, ≥20 weeks gestation, fluent in Norwegian or English | >19 | <20 weeks | Dietary counselling + pamphlets containing 10 dietary recommendations + hands-on cooking class + access to interactive website with information on nutrition during pregnancy | 82 items FFQ + 24 h recalls |
| Thornton et al. (2009) | USA | Journal of the National Medical Association | Obese pregnant women with singleton pregnancy | ≥30 | 12–18 weeks | Advised on a balanced nutritional regimen. | Daily food diary throughout pregnancy |
| Vesco et al. (2013) | USA | Obesity | Age >18, >8 weeks gestation (at first antenatal booking) | ≥30 | 7–21 weeks | Combination of diet and exercise recommendation + behavioural self-management. | 7 days food diary |
| Walsh et al. (2012) | Ireland | British Medical Journal | Secundigravid, singleton pregnancies, previous macrosomia of >4kg, aged <18 | Any | <18 weeks | Nutritional advice following a low glycaemic index diet | 3 days food diary |
| Wang et al. (2015) | China | Asia Pac J Clin Nutr | Diagnosed with GDM, age 22–38, no pregnancy-related complications, no history of diabetes, hypertension or GDM | Any | 24–28 weeks | Individualized dietary guidance | 24 h recalls |
| Wolff et al. (2008) | Denmark | International Journal of Obesity | Nondiabetic, nonsmoking, white, aged 18–45 | ≥30 | 15 weeks | Nutritional advice and provision of supplements | 7 days weighed food diary |

CAPI, computer-assisted personal interviewing; DASH, Dietary Approaches to Stop Hypertension; DEBI, diet, exercise and breastfeeding intervention; FFQ, food frequency questionnaire; GA, gestational age; GDM, gestational diabetes mellitus; IGT, intolerance glucose test; TIC, therapeutic lifestyle changes.
limitations. We assessed the risk of bias and methodological quality of all included studies. We assessed the type of dietary tools, their validity and identified factors associated with their use in a pregnant population. We were not able to provide details on the rationale for choosing various dietary tools in pregnancy and the methodology used due to the paucity of published information. Very few studies conducted validation studies, and the numbers were insufficient to generate any meaningful conclusions on validating SRTs in a pregnant population.

Dietary tools in pregnancy

Food diaries were used in about two-thirds of included studies; traditionally diaries were the most commonly used tool to report dietary intake in epidemiological studies [29]. They, however, still suffer from a number of limitations, which may lead to misreporting or under-reporting of intake data. Food diaries are more likely to under-report certain nutrients in women and obese participants [30]. They can also vary largely in the accuracy of details provided particularly when portion sizes and meals’ weight are not recorded [31]. Introducing food diaries over a long time (more than 3 days) is likely to lead to higher dropout rate, thus increasing the risk of bias [32]. In addition, participants are more likely to change their dietary habits when completing diaries for a long period reducing the diaries’ ability to capture habitual intake [33]. Three-day food diary was the most commonly used method, and only two studies used weighed diaries [11,15]. However, we record no clear explanation for such practice.

A third of included trials used an FFQ to assess dietary intake. The decision to use these FFQs seemed arbitrary. FFQs’ sensitivity to capture dietary changes in trial settings is generally trivial [34] and can be affected by a number of factors such as the sample size, population literacy, number of items in the FFQ, combination of food groups and the type of the dietary intervention introduced [9]. FFQs’ reliability in pregnancy is further undermined because of the instability of dietary intake. Differences in dietary requirement per trimester and common eating disorders such as hyperemesis all increase the intrarater variability in a pregnant population [35]. Some observational studies have confirmed the relative ability of an FFQ to rank individuals according to their dietary intake in a pregnant population [36–38]. However, the generalizability of this to interventional trials is still arguable.

The majority of included studies in our review adopted an FFQ that was validated in a similar population, and only two validated their questionnaires in the study population against other SRTs [13,24]. Although this is a common practice in most dietary studies [39], the increased inter-rater variability in pregnancy is likely to result in a higher random error when SRTs are used in validation studies. Consequently, it might undermine the validation process requiring a larger study sample or more diaries collected [30]. Objective biomarkers could also be used in validation studies [40];
CONCLUSION
Although self-reporting dietary assessment tools are widely used in interventional dietary trials in pregnancy, the quality and applicability of existing tools are low with little consideration to the particularity of a pregnant population.

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Conflicts of interest
There are no conflicts of interest.

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- of special interest
- of outstanding interest

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Implication for future research
The increased systematic and random reporting errors from the use of dietary tools in pregnancy need to be minimized. The use of combined dietary assessment tools should be evaluated to reduce the under-reporting bias [42]. Regression models could also be used to correct measurement errors in dietary assessment studies [43]. Such tools take into consideration the presumed systematic and within-person random variations to allow for a more accurate estimate of effect [43]. The applicability of these tools in dietary studies in pregnancy is still limited, and more work is needed in this field.

The majority of available biomarkers assess specific nutrient intake rather than consumption of food items [41]. The applicability of biomarkers is still limited by the gap of knowledge on their validity, reliability and reproducibility [44]. In our review, biomarkers were used in four studies, but only one study used specific serum biomarkers to assess the dietary intake of particular nutrients [22*]. Cost implications and invasiveness are other important factors to consider in trial settings [30].

Pregnancy imposes a number of specific challenges on dietary assessment in interventional studies. Establishing a link between diet and the condition of interest requires long-term follow-up before, during and after the pregnancy. Assessing dietary intake frequently might reduce patients’ motivation in pregnancy settings particularly for multiparous women who have less free time to engage in laborious methods such as weighed diaries. Assessment tools need to address the objective of the trial and capture the effect of diet on both the mother and the fetus.
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