Reviewer's report

Title: Antioxidant-rich dietary intervention for improving asthma control in pregnancies complicated by asthma: study protocol for a randomized controlled trial.

Version: 2 Date: 6 January 2014

Reviewer: Dean A. Sewell

Reviewer's report:

Major Compulsory Revisions/Responses

1) There is a discrepancy between the Abstract (mild, moderate or severe asthma) and p7 (mild or moderate/severe), so clarification is required as to whether three categories of asthma severity or two will be used.

2) I would suggest that there are too many references, some being unnecessary, such as a textbook reference (#2) to a definition of asthma. Is #5 an appropriate citation - is this not a secondhand opinion rather than reference to first hand experimental evidence (of 'a high level of oxidative stress in the lung')? There might be some attention to the quality of some of the literature cited, and, use of 'e.g.' to cite one, most appropriate reference, rather than several. One might also question why, for example, #62-66 are cited for the first time in the Discussion, and have not been previously introduced (i.e. in the Introduction/Background).

3) Methods (p8) - clarity required on whether the booklet 'healthy eating during pregnancy and lactation' intended for use in the control arm is the same as the 'Australian Guide to Healthy Eating for pregnancy' intended for the Intervention arm, and if not the same booklet, how can a Control arm participant not receive the current national Guide?

4) It would seem that Consent is being obtained at the same time/occasion as the participant being invited to take part in the study (p9). This contravenes at least good practice, if not ethical protocol, and participants would normally be given some time to consider their involvement after being informed, normally at least a day. In practice, one can see that participation in the trial only begins at a later date, by which time, the participant can withdraw, but nevertheless, the principle might be addressed or the timing of consent being obtained made more clear.

5) The randomisation is complex, and it is not clear how stratification can take place based on so many outcome measures (parity, asthma severity, and age, body mass index and vegetable intake) - greater detail should be given as to how this will be done, whether by an independent statistician and/or whether this procedure is computer driven, and what service/software will be doing this.

6) There needs to be comparability between a) the strategies that achieved 22%
dropout (wouldn't this be better reported as 78% retention?) and 80% compliance (p12) and b) the sample size discussion (p13) which talks about 'a 10% loss during the run-in period' - why wouldn't a 22% loss be estimated?, and a 'further 25% loss during the intervention period' - why wouldn't a 20% loss be estimated?

7) In the Discussion, health expenditure on asthma is raised, however, there do not appear to be any health economic outcome measures. There will be economic consequences for the participants (and despite the authors mentioning that fast food is expensive, one barrier to compliance is potentially the high cost of fresh fruit and vegetables, and there is no financial recompense for participants in the trial for this). Furthermore, there does not appear to be any attempt to assess the cost of the intervention/any cost-benefit analysis.

8) Perhaps little can be done about the design, but it seems that if the trial is to address asthma control in pregnancy, virtually half of the pregnancy is missed before the Randomisation/Intervention begins to be delivered at 18 weeks.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

'I declare that I have no competing interests'