Reviewer's report

Title: Safety and efficacy of a lifestyle intervention for all pregnant women to prevent excessive maternal weight gain: A cluster-randomized controlled trial

Version: 1 Date: 28 January 2013

Reviewer: Shakila Thangaratinam

Reviewer's report:

The authors have studied the effect of lifestyle and dietary interventions through a cluster randomised trial adding to the growing literature published in this area.

Methodology

1. The sample size calculation was changed half way through the trial rather than recruiting more practices to the control group. The power calculation did not take into account the clustering effect and this should be highlighted as the weakness of the trial.

2. The authors mention that intense counselling was provided, but from the manuscript, it appears that participants were contacted only twice. It is possible that knowledge of participation in the trial could have motivated the health care providers to provide additional input regarding weight management outside the trial protocol, accounting for the group doing well.

3. One major concern is the absence of data on compliance, especially for physical activity. It is difficult to ascertain the effect physical activity may have on the outcome. It is well documented that compliance for physical activity is poor in pregnancy and the observed benefit could solely be attributed to the dietary component. The work by Thangaratinam et al (BMJ 2012) has shown that diet based interventions consistently perform better than both diet and lifestyle.

4. May be preferable to use RR instead of OR.

Applicability:

I am uncertain if the intervention could be recommended in pregnancy to improve outcomes for the following reasons. Firstly, it is not clear if all components contributed to the minimal GWG or it was mainly due to diet. Secondly, in the absence of evidence that mixed interventions actually improve pregnancy outcomes, it may be better to limit the conclusion as follows: they may minimise GWG, but effect on pregnancy outcomes is unclear.

Level of interest: An article whose findings are important to those with closely related research interests

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