Reviewer's report

Title: A factorial randomized controlled trial to evaluate the effect of micronutrients supplementation and regular aerobic exercise on maternal endothelium-dependent vasodilatation and oxidative stress of newborns

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Reviewer: David Moher

Reviewer's report:

- In the abstract (page 2; Methods and design) the authors have described the Control Group as a placebo. Yet the authors indicate an ‘intervention’ Maltodextrine will be given to participants. I’m not sure why a placebo is considered in this study design. The placebo is also included in the graphical representation of the design (table 1, page 19). The description in the abstract and table does not match the description elsewhere in the manuscript – pages 5 and 6. The authors need to clarify and explain their proposed design.

- More generally, the authors need to provide a strong rationale as to why a placebo is being considered for this trial.

- On page 5 (Outcome variables) the authors should delete “first” and replace it with “primary”. Likewise, the authors should delete “second” and replace it with “secondary”.

- On page 7 (Analytic Plan) the authors should explicitly state whether the primary data analysis will be an intention To Treat (ITT) one or something different?

- On page 7 (Analytic Plan) the authors have not explicitly indicated whether they will complete an ‘interaction’ analysis such that they will examine the combined effects of both interventions (aerobic exercise; micronutrient supplementation). Clarification is required.

- The authors need to explicitly describe how they will achieve adequate allocation concealment (page 9, randomization).

- Also in page 9 (Randomization) the authors describe blinding. Can the authors clarify why blinding is relevant given the objective primary and secondary outcomes proposed for the trial? Is there confusion between blinding and allocation concealment? Clarification is required.

- The authors might also find CONSORT for pragmatic trials for reporting this trial (Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008:337:a2390.)