Author's response to reviews

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 newborn

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Author's response to reviews:

Cali, Colombia, November, 24, 2010

Professor

David Moher

Editors

Trials

RE: MS: 1488023423382489 “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 newborn”

Dear Editor,

Please find attached the revised version of the manuscript “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 newborn”. All authors have read and approved the paper, and declare that there is no conflict of interest with the subject of the manuscript. The observation by the reviewer have been taken into account y have been responded.

1- Question Reviewer 1: The protocol – Page 4, Study design, is described as
double blind. Yet, later on in the description, Page 11, the authors state “...it is not possible to blind the participating women.”. How is the trial double blind? If the research assistants are the only personnel blinded, is this not a single blind trial?

Answers to comment of Reviewer

Yes, this study is single blind trial.

2- Question Reviewer: In response to my previous review – trying to understand the rationale for the inclusion of a placebo in the control group – the authors indicate their desire to keep the micronutrient supplementation ‘hidden’ - I would call this procedure a ‘double dummy’, whereby investigators might be giving different number of injections, for example. Perhaps intervention A has 2 needles and intervention B has 3 needles. An investigator might add a third ‘placebo’ needle to intervention A to maintain the participant blind. This would be truly the case for a double blind trial. In the micronutrient protocol the authors state that it is impossible to blind the participants. Further clarification about the double dummy procedure is required.

Answers to comment of Reviewer

The placebo is used in the control group because we need to hide the micronutrients supplementation.

3- Question Reviewer: On page 8, part of the analytic plan, the authors state “Multiple imputation, compared to other case deletion strategies…… for missing data. Can the authors provide a reference for this statement.

Answers to comment of Reviewer

Add (3) References:


4- Question Reviewer: Randomization, the authors have provided the actual block randomization scheme “50 blocks with 8 women each”. Has the trial finished? If the trial is still ongoing the blocking scheme should not be included with the protocol description that is being considered for publication

Answers to comment of Reviewer
This sentence was eliminated the protocol description

5- Question Reviewer: On page 10, the authors describe issues pertaining to blinding. This needs to be a separate heading – Blinding - and not included within the Randomization heading.

Answers to comment of Reviewer
On page 10: Rewrite.

We thank the reviewers and the editor for taking the time to review our manuscript and look forward to your response.

Yours Sincerely,
The author’s