Author’s response to reviews

Title: Mothers After Gestational Diabetes in Australia Diabetes Prevention Program (MAGDA-DPP) post-natal intervention: study protocol for a randomized controlled trial

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Author’s response to reviews: see over
Dear Editors in Chief,

Thank you for forwarding on the reviewer’s comments for the manuscript entitled “Mothers After Gestational Diabetes in Australia Diabetes Prevention Program (MAGDA-DPP) postnatal intervention: study protocol for a randomized controlled trial” (Manuscript number: 1280965035104093).

We thank the reviewer for his valuable comments and suggestions for this manuscript.

Please find below our point-by-point response to the reviewer’s comments. We also have moved the list of abbreviations, the competing interests and authors’ contribution sections right after the Trial Status section as per editorial request. These sections were previously at the very end of the document. We also have made changes where necessary to the manuscript using tracked changes.

We trust these amendments will make this paper clearer for the reader.

Reviewer

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| The Primary Outcome is not quite clear to me - the authors talk about change in diabetes risk, as determined by changes in FPG, weight and waist circumference. The sample size estimate is based on changes in FPG. The authors should clarify if they aim to use FPG as the primary outcome or FPG, weight and waist circumference as Co-primary outcomes, which will finally have an impact on the study SAP and the way of alpha-spending. | We accept that the section ‘Primary Outcome’ was not clear. The section has been revised and now reads as: 

*The primary outcome is the change in diabetes risk, as determined by changes in FPG, weight, or waist circumference. A statistically significant change in any one of these three endpoints will be regarded as evidence of a change in diabetes risk. No adjustments to significance levels will be made for multiple testing. These co-primary outcomes will be assessed at baseline and 12 months for all women, and additionally at 3 months (or as soon as possible after the final group session) for the intervention participants only.*

In this revised passage we acknowledge the use of co-primary outcomes and address the issue of alpha-spending. The power calculations are based on changes in FPG and the sample size will provide sufficient power to also analyze changes in weight and... |
We anticipate that our responses address the points raised by the reviewer and that this manuscript is now acceptable for publication in Trials Journal.

With Kind Regards,

[Signature]

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