Author's response to reviews

Title: Evaluation of cardio-metabolic risk factors and the effect of a primary prevention lifestyle modification intervention on the development of overt cardio-metabolic disease in a young urban population in Sri Lanka (DIABRISK-SL)- protocol for a randomized controlled trial

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Version: 3 Date: 2 August 2011

Author's response to reviews: see over
Editors in Chief

Trials Journal

Re: MS: 1566922840549629

Evaluation of cardio-metabolic risk factors and the effect of a primary prevention life style modification intervention on the development of overt cardio-metabolic disease in a young urban Population in Sri Lanka (DIABRISK - SL)- protocol for a randomized controlled trial

Authors: Mahen Wijesuriya, Martin Gulliford, Laksha Vasantharajah, Giancarlo Viberti, Luigi Gnudi and Janaka Karalliedde

Thank you for giving us the opportunity to revise the above manuscript. We wish to thank the two referees for their helpful comments and advice which we have incorporated in the revised manuscript. As suggested, we have addressed all the questions raised by the reviewers and provide detailed replies on a separate page. We also indicate, in this page, the changes made to the text of the manuscript in accord with the reviewers comments and critiques.

Changes to the text of the manuscript have been highlighted in yellow in the revised paper. We feel that the revised paper is now significantly improved and we hope that you will now find the revised version of the manuscript suitable for publication.

Yours sincerely,

Dr M Wijesuriya, Dr Luigi Gnudi and Janaka Karalliedde
Reviewer one

We thank the reviewer for his/her comments and advice.

Reviewer's report:

Qn 1. Randomisation - please add a little more detail. Sequential or block?
Ans. We have now clearly stated that randomisation was performed sequentially and added more detail on the randomisation process.
Page 8 line 1-4 down

Ans. The urine sample will be an early morning sample before OGTT;
This is now clarified in page 9 line 2 down

Qn 3. Children - how will the lifestyle advice be given to the children - to them? directly, to the parents only or to parent and child? If to the young person, how will the advice be adapted? Are there any precautions to ensure that children continue to grow at a normal rate?
Ans. Advice will be given to the parent and the child jointly. We have added more detail on this and the precautions/measures the study investigators will take to ensure there is no detrimental effect of the intervention on normal growth.
Page 9 line 1-5 up
Qn 4. Page 8 last line / page 9 first lines. This is confusing. One sentence says all subjects (presumably all in the intensive group only?) have 3 monthly telephone contact and then the next sentence says the number of 1 to 1 sessions per year is 4, with 2 of these face to face. Please express more clearly.

Ans. This section has been re-written and hopefully is now clearer to understand

Page 10 line 2-3 down

Qn 5. Page 10 - new onset OGT/IFG - I think IFG is 6.1 - 6.9 or 5.6-6.9 mmol/l not to 7.0 mmol/l

Ans. We have corrected this error in the manuscript and now give the correct ranges for IFG which are as stated by the reviewer

Page 11 line 7 up
Reviewer two.

We thank the reviewer for his/her comments and advice.

Major compulsory revisions:

Qn 1. Methods: age group: 5–40 years — wide range age group has been selected.
Cut-off values for 2 risk factors (BMI, WC) have been given only for age groups 10–17 years and 18–40 years, whereas the study age group is 5–40 years.

Ans. The cut-off values for BMI and WC are now stated for 5-40 years
Page 6 line 8-10 up

Qn 2. It is not clear whether biochemical investigations will be performed both at baseline and at follow up visits?

Ans. We have amended the manuscript to more clearly state that baseline measures will be taken and that measures will be repeated at 12 monthly follow up visits.
Page 8 line 6-7 down

Qn 3. Provided methods for glucose, lipid profile, hsCRP, creatinine, MAU, insulin.
Study subjects are recruited based on the presence of 4 risk factors (BMI, WC, FHDM, Physical inactivity), details on H/o DM, CVD, HTN are collected, but it is not clear whether the above investigations are done at the baseline, comparison is not possible without baseline details. Moreover, subjects might have dysglycaemia, elevated BP or cardiovascular risk factors during recruitment itself. The development of diabetes or CVD is related to the baseline risk.

Ans. We have amended the manuscript to clarify that all these measures will be performed before randomisation (i.e. at baseline).
Page 8 line 6-7 down
All subjects are healthy and not on any medications that affect blood pressure, glucose or lipid levels. The effect if any of baseline risk factors on end-points will be evaluated in analyses.

Page 4 line 3-4 up.

The laboratory methods used for the above measurements are now expanded as per the reviewer’s advice. Page 8 line 1-8 up and page 9 line 1-2 down

Minor essential revisions:

Qn 5. Methods: 1st line, sentence is not clear “Parallel group clinical at a single………..”

Ans. This has now been re-written as

Page 2 line 8-9 down

Qn 6. n = 23,298 (M: F?)

Gender data is now presented

23,298 (males 47% females 53%)

Page 2 line 11

Qn 6. Background: 2nd paragraph, 2nd sentence is not clear. “suggested that 10.8 subjects with IGT ………….. 6.4 subjects with lifestyle intervention to prevent once (one) case of T2DM.

Ans. This sentence has been re-written so that it is clearer to the reader.

Page 3  line 2-4 up
Qn 7. Total number of subjects: 4500 mentioned in abstract, but 4600 mentioned in the text.

Ans. This has been amended to 4600

Page 2 line 15 down

Qn8. Intervention and goals:

1st paragraph, last line “the Indian Diabetes Prevention Programme (IDDP) (5)”.

It is ‘IDPP’ and the reference should be (6). IDPP reference has been quoted wrongly throughout the text.

Ans. We have corrected this error and the IDPP study is now quoted/referred correctly.