Author’s response to reviews

Title: Effect of Prenatal EPA and DHA on Maternal and Cord Blood Insulin Sensitivity: A secondary analysis of the mothers, omega 3, and mental health study

Authors:
Joey England (joey.a.england@uth.tmc.edu)
Joses Jain (joses@pinonperinatal.com)
Bradley Holbrook (Bradholbrook@gmail.com)
Ronald Schrader (RSchrader@salud.unm.edu)
Clifford Qualls (CQualls@salud.unm.edu)
Ellen Mozurkewich (EMozurkewich@salud.unm.edu)

Version: 2 Date: 04 Nov 2019

Author’s response to reviews:

Joey A. England, MD
Assistant Professor
Maternal-Fetal Medicine
Department of Obstetrics, Gynecology & Reproductive Sciences
McGovern Medical School

November 1, 2019

Dear Dr. McMillan and BMC Pregnancy and Childbirth:

Thank you for the opportunity to submit our revised manuscript for consideration of publication. We have carefully reviewed each of the editor’s and the reviewers’ comments and have modified the manuscript to address them.

In response to the editor’s and the reviewer’s comments:

2. Please confirm whether patients consented to their samples being used in this secondary blood sample analysis. Please confirm whether informed consent obtained from all participants was written or verbal, and clearly state this in your Methods and Ethics approval and consent to participate sections. If verbal, please state the reason and whether the ethics committee approved
this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

This study was approved by the IRB of the University of Michigan Medical Center under the title:

Does EPA or DHA prevent depressive symptoms in pregnancy and postpartum?

(HUM00004684)

All subjects signed full written informed consent at the time of the enrollment in the trial. The consent language included the following statement: “The blood and urine tests will measure fatty acids, lipids and inflammatory markers.” IRB approval for the secondary blood sample analysis described in this manuscript was obtained through submission of an amendment to the original study (HUM00004684). The IRB did not require study subjects to be re-contacted for consent for this secondary blood sample analysis because adiponectin and leptin assays were felt to be covered under the consent language stating that blood samples would be evaluated for “inflammatory markers”.

The secondary blood sample and data analyses described in this study were carried out at the University of New Mexico where the secondary blood sample analysis was deemed exempt by the HRPO (HRPO 12-466). Access to the de-identified blood samples and data was provided to the University of New Mexico under a maternal transfer agreement and a data sharing agreement.

We have edited the “Ethics” section of the manuscript accordingly.

3. Please include a statement in your Funding section describing the role of the funding body in the design of the study, the collection, analysis, and interpretation of data and in writing the manuscript.

We have added a statement regarding the role of the funding sources.

4. The Acknowledgements section in your Declarations is where you acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section. Your current statement does not acknowledge anyone, it just contains the name of an institution. Please amend this.

We have updated the acknowledgment section, as recommended.
5. Please move the statement regarding the presentation of your research as a poster, from the 'Authors contributions' section to the 'Acknowledgements'.

We have moved this statement to the Acknowledgment section, as recommended.

6. Please move your 'Figure legends' to after the references.

We have moved the legends as you have requested.

7. At this stage, please upload your manuscript as a single, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

We have uploaded the final version of the manuscript as you have requested.

Reviewer reports:

Stephen Contag (Reviewer 2): 1. Summarize the manuscript's content.

This manuscript is second submission of a secondary analysis of "The Mothers, Omega-3, and Mental Health Study," using the same group randomization of primarily EPA, DHA or placebo. The authors also included 25-hydroxycholecalciferol levels as an independent variable. Outcomes measured were surrogates for insulin sensitivity: 1) adiponectin levels, 2) leptin levels, and 3) adiponectin leptin ratio (ALR), levels. Increasing levels of outcomes 1 and 3 are associated with increased sensitivity and increased levels of outcome 2 with decreased sensitivity.

We appreciate the reviewer’s comments.

2. The perceived limitations were adequately addressed:

   1. The authors have structured their manuscript to fit the title emphasizing DHA and EPA acid supplementation and the conclusions are consistent with what is presented in the results.

We appreciate the reviewer’s comments.

   2. The tables are easier to understand and the overall presentation of results is appropriate.

We appreciate the reviewer’s comments.
3. The authors have chosen to include data on vitamin D in their manuscript. Although I do not think it is relevant to this manuscript, as currently presented, it does not detract from the readers ability to understand what the study is about and what was done.

We appreciate the reviewer’s comments.

Raylton Chikwati, Bsc, Msc (Reviewer 3): Please include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format.

We received no comments from this reviewer.

Thank you for consideration of our research for publication.

Joey A. England, MD

Assistant Professor
Maternal-Fetal Medicine
McGovern Medical School University of Texas Health Science Center at Houston