Author’s response to reviews

Title: Acceptability and utilization of a lipid-based nutrient supplement formulated for pregnant women in rural Niger: a multi-methods study

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Author’s response to reviews:

Editor Comments:

In addition to the reviewers’ comments below please address the following editorial concerns:

Comment 1. Section headers

Please ensure that your section headers adhere to the submission guidelines
(https://bmcnutr.biomedcentral.com/submission-guidelines/preparing-your-manuscript/research-article)

- Change "Methods and materials" to "methods"

- Change "conclusion" to "conclusions"

Response: As suggested, the section headers have been corrected as follows: “Methods and materials" changed to "methods" (line 81) and "Conclusion" changed to" Conclusions” (line 351).

Comment 2. List of abbreviations
Please remove the list of abbreviations from the declarations and insert them as a separate section between conclusions and declarations.

Please ensure that the list of abbreviations include all abbreviations and acronyms "for instance EPI-E"

Response: As suggested, the list of abbreviations have been moved from the declarations and inserted as a separate section between conclusions and declarations (lines 370-376). In addition, we have reviewed the manuscript in full to ensure that the list of abbreviations is complete. However, we note that “Epi-E” is not an abbreviation or acronym. Epi-E is the full name of the experimental product using this phase of testing and thus not included in the list of abbreviations.

Comment 3. Ethics approval and consent to participate

Please include your ethics approval reference number in this section

Response: As suggested, we have included the reference numbers for each ethics approval in the Ethics Approval and Consent section of the declarations (lines 384-388).

Reviewer reports:

Susana Matias (Reviewer 1): The authors have partially responded to my initial comments. However I still think there are several issues to resolve in this manuscript. Please find further comments below.

Response: We thank the reviewer for this thoughtful second review and appreciate this opportunity to further improve the manuscript. We have addressed each point below.

Methods

Lines 152-153: How was this recorded? Please add details for the reader to assess how objective was this measurement.

Response: We confirm that the amount of the test meal consumed was measured by weighing the test meal volume before and after the period of consumption.

As suggested, to provide more detail on this objective measurement, we have revised the text as follows (lines 150-152): “Interviewers weighed the amount of Epi-E/maize porridge mixture that each participant was served and the amount remaining after 15 minutes. The portion consumed was defined as the difference between the starting and ending volume to the nearest gram.”
Lines 153-156: In my experience to use Likert scales with low educated populations can be quite challenging, how did it work in your sample? Did you use any visual aids?

Response: We thank the reviewer for this comment and agree the use of hedonic scales must be carefully executed in populations with low education and literacy. For this reason, our study combined the use of the hedonic scale with visual representations to aide respondents. The hedonic sample and accompanying visual aides were pilot tested and found to be well understood by the study population.

To clarify this point for readers, we have revised the text as follows (lines 156-158): “The 5-point scale was visually depicted using a range of emoticon faces (very unhappy to very happy) that have been used to measure food acceptability in illiterate populations (Cohuet et al. 2012; Hess et al. 2011; Iuel-Brockdorf et al. 2015).”

Lines 189-190: The text on the explanation of the hypothesis testing is not quite correct. You hypothesized that the consumption will be at least 50% (lines 181-183), and what you need to test is whether your observed level of consumption is no less than 50%, beyond chance. Statistically this is not the same than what is included in lines 189-190.

Response: We understand the reviewers comment and confirm that the sample size calculation was based on a one-sided test while the statistical analysis is based on a two-sided test of significance. The reviewer is correct to note that these are statistically different, however, we believe use of two-sided test of significance in the analysis is in fact a more conservative approach than using a one-sided test. While this results in a minor discordance between approaches, both methods are transparently presented to readers (lines 185-187 and lines 193-194). Use of the two-sided test for analysis is recommended here as it is the more conservative approach and does not introduce bias.

Results

Lines 207: Please start this section indicating your actual sample size.

Response: We thank the reviewer for this comment and regret that we are not able to revise as suggested. As is shown in Table 2, the actual sample size varies from 26-28 women, depending on the assessment day. Unfortunately, we found no way to concisely represent this information in the text and do not feel it is necessary to repeat information already presented in tables. If acceptable to the editors, the actual sample size for each assessment will remain reported only in Table 2 to avoid repetition of results.

Lines 214-215: How was "important variation" assessed? What was the objective way to measure variation? Please add that information here.
Response: The extent of variation can be objectively assessed using the standard deviations provided in all tables. Standard deviations are standard measures of dispersion, and this information can be used to understand whether the distributions of two parameter overlap, indicating no statistically significant difference between assessments.

We agree with the reviewer that the word “important” may not be precise enough. We have therefore revised the text to read as follows (lines 218-219): “There was no significant variation in results between days (day 1 vs. day 2) or between time periods (June (Ramadan) vs. September (non-Ramadan)).”

Lines 217-218: Based on the text in lines 181-183, the hypothesized level of consumption was 50%, not 75%. Is this a typo? If not a typo, I strongly suggest the authors to consult with a statistician. This type of consultation seems needed to improve the level of evidence this study can provide.

Response: We thank the reviewer for identifying this error. We confirm this was a typo and have corrected to the text to read as follows (lines 221-222): “Mean consumption during both test meals was significantly greater than the null hypothesis of 50% consumption (p < 0.05).”

Lines 221-222: The information included seems to be anecdotic, that is not from a structured data collection process, or was there some kind of data collection tool administered to interviewers? If no actual data collection was done, please indicate that is anecdotic information only.

Response: We apologize for this omission. We confirm that the protocol required all interviewers to provide textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective. These data are not anecdotal but rather qualitative data that represent part of the study protocol and analyzed in the same manner as other qualitative data (analytical approach described on lines 191-195).

To correct this omission in the presentation of the methods, we have added the following text to the Methods section as follows (lines 181-183): “All interviewers provided textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective.”

Lines 226-227: What does "little variation" mean? Please add more objective information here.

Response: We agree with the reviewer that the word “little” may not be precise enough. We have therefore omitted this term and revised the text to read as follows (lines 230): “Participants reported consuming a mean of 14 sachets as prescribed.”
Response: We thank the reviewer for highlighting these areas for clarification. We have identified the missing words and removed the word “tendency”.

The revised text reads as follows (lines 231-233): “The mean (SD) number of sachets consumed per day by participants were, however, observed to be higher in June (Ramadan) than in September (non-Ramadan) (1.7 (0.5) sachets/day vs. 1.1 (0.3) sachets/day) (Table 4).”

Response: As noted above, we apologize for this omission. We confirm that the protocol required all interviewers to provide textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective. These data are not anecdotal but rather qualitative data that represent part of the study protocol and analyzed in the same manner as other qualitative data (analytical approach described on lines 191-195).

To correct this omission in the presentation of the methods, we have added the following text to the Methods section as follows (lines 181-183): “All interviewers provided textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective.”

Response: As suggested, without the addition of inferential statistics, we have revised the text as follows (lines 269-273): “Women estimated that they would be willing to pay on average (SD) $0.31 (0.29) per sachet, compared to $0.05 (0.05), the average amount last paid for a daily prenatal micronutrient supplement and $0.31 (0.19), the average amount last paid for a serving of their favorite snack food.”

Discussion
Lines 313-315: So there was systematic data collection from interviewers? If so, please include that information in the Methods section. If not, please do not include this as a strength of the study. Any non-systematically collected data can provide biased information.

Response: As noted above, we apologize for this omission. We confirm that the protocol required all interviewers to provide textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective. These data are not anecdotal but rather qualitative data that represent part of the study protocol and analyzed in the same manner as other qualitative data (analytical approach described on lines 191-195).

To correct this omission in the presentation of the methods, we have added the following text to the Methods section as follows (lines 181-183): “All interviewers provided textual field notes regarding their perception of the product acceptability for further triangulation of data from the interviewers’ perspective.”

Lines 329-330: And also interviews comments!

Response: As suggested, the text has been revised as follows (lines 334-335): “Second, social desirability to provide positive responses may have positively biased participant responses and interviewer field notes [47].”

Lines 331: In the Discussion is where the reader learns that you weighted meals. I asked for this information above, please add details in the Methods section.

Response: As suggested by the reviewer and noted above in response to the earlier comment, we have revised the text of the Methods section as follows (lines 150-152): “Interviewers weighed the amount of Epi-E/maize porridge mixture that each participant was served and the amount remaining after 15 minutes. The portion consumed was defined as the difference between the starting and ending volume to the nearest gram.”

Lines 322-341: If the decision is made not to include further objective, statistical testing information then I suggest you add that to the list of limitations.

Response: As suggested by the reviewer, we have revised the Discussion text to note the absence of extensive statistical testing as a limitation as follows (lines 341-344): “Fourth, the study did not assess participants’ dietary intake or gestational age at enrollment, and did not conduct statistical testing for comparisons other than the primary aim.”

Daniela Saes Sartorelli (Reviewer 2):
The paper "acceptability and utilization of a lipid-based nutrient supplement formulated for pregnant women in rural Niger: a multi-methods study" aimed to assess the acceptability and utilization of a 40gLNL formulation (Epi-E) with increased micronutrient content relative to the recommended daily allowance among pregnant women in rural Niger.

It is an interesting paper. However, there are some limitations not discussed by the authors.

First of all, Table 1 presents the nutrient composition of Epi-E. For some nutrients, the dose is higher than the RDA. For which reason? Since it is well described in the literature that there is no advantage of nutrient daily doses higher that the RDA.

Response: We thank the reviewer for highlighting this point of confusion. We confirm that the higher micronutrient dose was provided based on the findings from Burkina Faso where a higher dose prenatal MMN-fortified food supplement was shown to increase birth length compared to MMN supplementation alone. This rationale for the dosing selected in presented in the Methods section (currently lines 107-109).

More than that, the authors did not mention of the doses are higher that the UL. This would be a problem. So, I suggest that in methods and discussion this topic should be deeply discussed.

Response: We agree with the reviewer that micronutrient doses above the tolerable upper intake level (UL) would not be safe, and we confirm that no micronutrient in this study was provided at a dose higher than the UL, as shown in Table 1.

Another limitation of the study is that the authors did not evaluate the impact on the adequacy of nutrient intake in those women. There were no data on food intake? If not, please discuss this topic. In the conclusion, the authors should describe that future studies are necessary to test the effect on the adequacy of nutrient intake, and on maternal and infant outcomes

Response: We confirm that this small, formative study did not collect dietary intake data, and we agree that this omission is a limitation to understanding the supplement’s impact on adequacy of nutrient intake. As suggested by the reviewer, we discuss this topic in the Discussion section as follows (lines 341-344): “Fourth, the study did not assess participants’ dietary intake and gestational age at enrollment, and did not conduct statistical testing for comparisons other than the primary aim.”

As suggested, we have also revised the Conclusion text to identify this as a study limitation. The revised text reads as follows (lines 365-367): “The Epi-E formulation will be tested as a potential strategy to improve the adequacy of nutrient intake and birth outcomes among pregnant women in this context.”