Author's response to reviews

Title: Efficacy of Moringa oleifera leaf powder as a hand-washing product: a cross-over controlled study among healthy volunteers.

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Author's response to reviews: see over
Dear Dr. Rowles,

Re: Efficacy of *Moringa oleifera* leaf powder as a hand-washing product: a cross-over controlled study among healthy volunteers. (revision)

We were pleased to receive your reply of 29/11/13 and are delighted to enclose our revised manuscript. We set out our response to specific comments in the text below.

Reviewer #1

Major Compulsory Revisions

1) The comment regarding causes of diarrhoea has not be satisfactorily addressed— the first paragraph of the Background implies that all diarrhoeal disease is microbial in origin (e.g. "Diarrhoea is caused by bacteria, viruses and protozoa, mainly found in human faeces which are spread from the stool of one person to the mouth of another.") and while it may be true that this is the most common cause of diarrhoea it is not the only cause and this should be clarified in the text.

*We have clarified this issue in the first paragraph of the Background and we hope that it is now clear for the readers.*

Discretionary Revisions

1) While I understand that the protocol follows that of the European Committee for Standardization EN 1500 and that this protocol recommends the use of 12-15 subjects in the study this does not actually address my comment. My comment is in relation to the power of the study that was completed. The authors state that “…thus allowing a considerable reduction in sample size while at the same time retaining statistical power.” however no evidence of the statistical power is given.

*We apologized that we only described the statistical test used and number of subjects required for the study following the EN guidelines but we did explain in detail why we use these numbers. We tested the mean log reduction factor of the new product compared with the reference product by using the Wilcoxon matched-pairs signed-rank test. Because of the confirmative nature of the test on*
this application, the level of significance is set at p=0.1. The test is to be used one-sided. The discrimination efficiency of the test procedure described has been set to detect a difference between the two mean log reduction factors of approximately 0.6 log at a power of 95%. We have added this information in the manuscript at the end of the Statistical Analysis section.

2) Origin of Moringa oleifera product – while the argument about use of a commercial product is a valid one in relation to use of a product that might actually be used in practice however the authors response does not actually answer the comment I raised. That comment relates to the verification of origin, level of contaminations etc for the product used. This information should have been obtainable from the manufacturer and I would have liked to have seen more information provided in the manuscript.

We tried to get this information from the manufacturer but after several attempts they refused to provide any information about the manufacturing process. We have openly provided in the manuscript all the information that we have about the plant. We believe that the important message is that we have observed the same results using different batches from this product as we had to buy it at different times, and we believed that they follow the European Community guidelines for manufacturing and control processes.

Reviewer #2

I have one recommendation for a discretionary change. In Discussion, paragraph 3 sentence 2, I suggest that that last two words, ‘better results’ be replaced with something like ‘optimal results’ or ‘the best results’.

We appreciate this comment and we have made the changes in Discussion, paragraph 3.

Editorial comments:
Please confirm whether your trial was registered in a publicly available registry, and include the resulting trial registration number at the end of your Abstract. Please note that we only accept registration numbers issued by registries that meet all of the ICMJE criteria (http://www.icmje.org/publishing_10register.html). Registries which meet the requirements of the ICMJE include WHO Primary Registries (http://www.who.int/ictrp/network/primary/en/index.html).

The WHO definition of a trial is: “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
We did not register this study as a trial because it is a laboratory-based study that aims to measure the bacterial reduction in artificially contaminated hands; therefore in this study we are not measuring any health outcome.

We look forward to hearing from you regarding the result of this resubmission; we believe that addressing the reviewers’ comments has strengthened our submission. If we can provide any further information about our methods or results then please feel free to contact us at the address above.

Yours sincerely,

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