

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.
AUTHORS	Manjang, Buba; Hemming, Karla; Bradley, Chris; Ensink, Jeroen; Martin, James; Sowe, Jama; Jarju, Abdou; Cairncross, Sandy; Manaseki-Holland, Semira

VERSION 1 – REVIEW

REVIEWER	Ayodeji A. Fasoro Afe Babalola University, P.M.B. 5454 Ado-Ekiti, Nigeria
REVIEW RETURNED	23-May-2017

GENERAL COMMENTS	<p>This is a good study attempting to summarise an intervention implementation and baseline data of the first African community-level weaning-food hygiene intervention programme.</p> <p>COMMENTS</p> <ol style="list-style-type: none">1. The authors should ensure that numbers 1 – 9 are written in words where necessary. Mistakes were made in different places all through the manuscript.2. Too many keywords. I think 3 – 10 should be enough.3. Background is too brief. More information is needed on what is known about general food handling practices of mothers of under-5s in the Gambia; and the most prevalent foodborne diseases of under-5s in the Gambia.4. Page 8: “ARI” was not used previously. Write out the abbreviation in full.5. CRR was 357(SD+59)??? CRR was 357±59.6. Of what importance is “a UK epidemiologist” to the study in the randomisation process?7. “...a statistician in the UK”??8. Page 9. Footnote can still be on the same page.9. Page 10, line 38 “...to all the village...” villages.10. Page 15, line 29 “The majority of the mothers were farmers and illiterate.” Include frequency/percentage11. Page 15, line 49. “Animations from South Asia were used...” Was any permission needed/obtained to use these materials?
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	<p>12. Page 19, line 8. "PHOs, TCs" abbreviations already known.</p> <p>13. Both discussion and conclusion lack quantitative data. Kindly include figures (frequencies, percentages, etc.)</p> <p>14. Rewrite title of Table 1</p> <p>15. No need of underlining words in Table 3</p> <p>16. The column heading of Table 5 needs to be aligned.</p> <p>17. Table 5: "RTI" What does it mean? Nowhere has this been mentioned in the manuscript.</p> <p>18. Table 6 may not be necessary. This is subject to the editor's decision.</p> <p>19. I recommend that the statistical analysis of the research be improved.</p> <p>20. The paper requires improvements to the English language within the manuscript before being published.</p>
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REVIEWER	Sarker Masud Parvez International Centre for Diarrhoeal Disease Research, Bangladesh [icddr,b]
REVIEW RETURNED	01-Jun-2017

GENERAL COMMENTS	<p>This is a timely and important trial to evaluate public health interventions for weaning food. There is a critical need for this trial to learn about the reduction of food contamination. The design of the trial has therefore been highly appreciated in the field and the authors should be congratulated for designing an excellent trial that would provide important new data for designing the food intervention at scale.</p> <p>I have no major criticisms, but several points of clarification that would strengthen the manuscript if addressed:</p> <ol style="list-style-type: none"> 1. In the intervention section, you mentioned that the intervention component was theory based and took lessons from Nepal and India to design. Later you described two theoretical frameworks that were used to design the intervention. I'm just wondering where was the link between lessons learned from India and Nepal and 2 theoretical frameworks? 2. The study setting is in Gambia but design based on Asian context, is there any specific rationale? If so, little explanation might be necessary in the draft. 3. How did the authors generate the clusters, is there any buffer zone to avoid spillover effect? Please clarify in the method. 4. I did not find anything related to data analysis in the method section. 5. My understanding is that the author precisely describes the intervention design, sample size calculation but what is the primary outcome of interest? I understand there is a lot to go but little description of outcome parameter would be helpful. 6. Intervention teams were formed based on literacy, why? Is there any specific rationale? Did they receive any training? If so, how long? What is the intensity of the household visit?
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	<p>Can the authors explain a bit more the extent of the training given?</p> <p>7. In the table 5, you reported diarrheal and RTI data, but did not found in the result section. Is this ARI or RTI, be consistent throughout the manuscript?</p> <p>8. In the figure 1, it mentioned that control arm received "use of water in home based gardening campaign", it seems like they will also receive some sort of intervention. Is this active control or passive control? Is there any visit by intervention team? Better to elaborate this control issue in the method section.</p>
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REVIEWER	Laura Schwab Reese University of Colorado Denver, CO, USA
REVIEW RETURNED	27-Jun-2017

GENERAL COMMENTS	<p>I appreciate the opportunity to review this manuscript. As the statistical reviewer, the topic is outside my area of expertise. However, I found the manuscript easy to follow and pleasant to read. In addition, I appreciated the comprehensive reporting of the intervention development and implementation. I was able to easily follow the progression of the intervention activities across the five days.</p> <p>Overall, I was satisfied with the methods and reporting of methods in this article. I have a few suggestions that I hope will improve the quality of the manuscript.</p> <p>1. I would appreciate additional information regarding the qualitative methods. All other aspects of the intervention development and data collection were extensively documented. As a result, a single sentence detailing the qualitative methods feels incomplete. It would be beneficial to know more about the training of the individual(s) who completed the analysis, the process for developing themes/codes, and the analysis of these themes so that it is possible to evaluate the appropriateness of the methods.</p> <p>2. It may be beneficial to conduct formal statistical comparison of the intervention/control villages and individuals. Without this analysis, it is not appropriate to state that the villages and families were well-balanced between the arms.</p> <p>3. Given the lack of clarity around the qualitative methods, it is difficult to evaluate the qualitative findings. Without additional context, it is not clear if the quotes are representative of opinions expressed by multiple people or if they represent a single point of view. It may be beneficial to narrow the themes/sub-themes reported and focus on the most important results. As written, it is not immediately clear from the results in Table 6 that "drama, animation, songs, stories, and handwashing demonstrations using GlowGerm appeared much more effective than the traditional communication..." (Page 16).</p> <p>Overall, the qualitative methods and results feel incomplete. As written, it is not clear that these methods substantially contribute to the overall manuscript. If it is not possible to improve the reporting in</p>
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	this area, it may be possible to remove these sections and focus on the other strengths of the paper.
REVIEWER	Irina Chis Ster St. George's University of London
REVIEW RETURNED	04-Sep-2017
GENERAL COMMENTS	<p>This paper describes in essence the protocol of a clustered randomized clinical trial investigating the effect of a series of public health interventions mainly targeting weaning-food which aim at lowering diarrhea proportions or rates among children under 5 years of age in Gambia. Descriptive baseline data are also presented as well as details on trial's logistics and implementation.</p> <p>Apart from the sample size calculation which seems to having been done using the correct methodology, there aren't any statistics presented (by means of p-values and uncertainty). These are hierarchical data and even comparisons at the baseline require multi-level methodology to account for this feature of the data. I am not entirely sure wheather this presentation can make a scientific paper on its own - rather a report maybe? This is a well written piece of work but all these details can be included in the Supplementary Information of an ample paper presenting the actual results of the trial.</p> <p>I have no statistical issues at the moment as there aren't any in this presentation. As for its publication, I cannot recommend rejection as I have a very good opinion about it. I just question its suitability to be deemed as a scientific paper as opposite to a report.</p>

VERSION 1 – AUTHOR RESPONSE

PART I

Reviewer(s)' Comments to Author:

Reviewer: 1

Not all the objectives of the study were fully described in the result section. For example, the prevalence of diarrhoea admission was not mentioned in the manuscript.

Other comments are in the attached file.

Authors

This is a baseline manuscript and not the trial outcome reporting. There seems to be a misunderstanding that the trial objectives are the objectives of this study. Therefore where it says "The primary objective of the main cRCT trial is to investigate the effects of the complex public health community intervention that sought to improve mothers' weaning-food hygiene practices. We further sought to investigate the effect of the intervention on the level of microbiological contamination in food and in water ready for child's consumption; and to establish the prevalence of diarrhoea and respiratory symptoms, and diarrhoea admission, as reported by the mothers." this refers not to the objectives of this paper, but rather the trial for which we are describing the intervention and baseline. We have amended the paragraph to clarify this.

Reviewer: 2

Best of luck !!

Authors: Thank you

Reviewer: 3

I appreciate the opportunity to review this manuscript. As the statistical reviewer, the topic is outside my area of expertise. However, I found the manuscript easy to follow and pleasant to read. In addition, I appreciated the comprehensive reporting of the intervention development and implementation. I was able to easily follow the progression of the intervention activities across the five days.

Overall, I was satisfied with the methods and reporting of methods in this article. I have a few suggestions that I hope will improve the quality of the manuscript.

1. I would appreciate additional information regarding the qualitative methods. All other aspects of the intervention development and data collection were extensively documented. As a result, a single sentence detailing the qualitative methods feels incomplete. It would be beneficial to know more about the training of the individual(s) who completed the analysis, the process for developing themes/codes, and the analysis of these themes so that it is possible to evaluate the appropriateness of the methods.

Authors:

Based on this comment and the one that comes later, we have removed the qualitative sections. We felt the addition of too much on this one FGD in this paper would not be productive. We will aim to add this to a set of qualitative data about the whole intervention in a qualitative paper.

2. It may be beneficial to conduct formal statistical comparison of the intervention/control villages and individuals. Without this analysis, it is not appropriate to state that the villages and families were well-balanced between the arms.

Authors

Thank you for this suggestion. However, this is a trial baseline data. According to CONSORT statement reporting recommendations followed by BMJ group of journals, using statistical tests between the arms is not recommended and therefore, we are unable to follow this suggestion and if conducted cannot report it.

3. Given the lack of clarity around the qualitative methods, it is difficult to evaluate the qualitative findings. Without additional context, it is not clear if the quotes are representative of opinions expressed by multiple people or if they represent a single point of view. It may be beneficial to narrow the themes/sub-themes reported and focus on the most important results. As written, it is not immediately clear from the results in Table 6 that "drama, animation, songs, stories, and handwashing demonstrations using GlowGerm appeared much more effective than the traditional communication..." (Page 16).

Overall, the qualitative methods and results feel incomplete. As written, it is not clear that these methods substantially contribute to the overall manuscript. If it is not possible to improve the reporting in this area, it may be possible to remove these sections and focus on the other strengths of the paper.

Authors

Thank you - as comment above – removed these sections.

Reviewer: 4

This paper describes in essence the protocol of a clustered randomized clinical trial investigating the effect of a series of public health interventions mainly targeting weaning-food which aim at lowering

diarrhea proportions or rates among children under 5 years of age in Gambia. Descriptive baseline data are also presented as well as details on trial's logistics and implementation.

Apart from the sample size calculation which seems to have been done using the correct methodology, there aren't any statistics presented (by means of p-values and uncertainty). These are hierarchical data and even comparisons at the baseline require multi-level methodology to account for this feature of the data. I am not entirely sure whether this presentation can make a scientific paper on its own - rather a report maybe? This is a well written piece of work but all these details can be included in the Supplementary Information of an ample paper presenting the actual results of the trial.

Authors

There seems a misunderstanding about the purpose of this paper. This is not a protocol paper. The baseline comparison cannot be statistically calculated due to the CONSORT statement as per comments above.

I have no statistical issues at the moment as there aren't any in this presentation. As for its publication, I cannot recommend rejection as I have a very good opinion about it. I just question its suitability to be deemed as a scientific paper as opposite to a report.

Authors

We understand from the editor and other similar papers that this is indeed classified as a scientific paper since new data from baseline and implementation of the intervention are described.

PART II

I have no major criticisms, but several points of clarification that would strengthen the manuscript if addressed:

1. In the intervention section, you mentioned that the intervention component was theory based and took lesson from Nepal and India to design. Later you described two theoretical framework that were used to design the intervention. I'm just wondering where was the like between lesson learn from India and Nepal and 2 theoretical frameworks?

Authors

We have clarified the section according to this comment. The theoretical frameworks were used in the Nepal and India studies and therefore by using these same theories we have use similar concepts with the Nepal and India studies allowing a great deal of similarities.

On page 12 it says: "As with the India and Nepal programmes, we focussed on the use of performing arts (using culturally ingrained styles of drama and songs),¹⁹ competitions and environmental cues²⁰ to deliver the HACCP corrective measures and motivational drives."

On page 15 it says: "Stories, songs, posters and animations from previous relevant programmes in India and Nepal were transferable from Asia to our African setting and the tools were easy to adapt within 6 weeks (including staff training, refining of the material, field testing and piloting)."

2. The study setting is in Gambia but design the based on Asian context, is there any specific rationale? If so, little explanation might necessary in the draft.

Authors

The rational is the application of the theories we wanted to adopt in another tested setting.

For clarification we have added on page 15: The intervention components and delivery package were theoretically-based, and informed by the local context from our formative research, and by the

lessons/tools from community interventions in handwashing studies in India¹⁴ and weaning-food hygiene in Nepal.⁸ The latter employed the same theoretical models in similar study questions. The

3. How did the authors generate the clusters, is there any buffer zone to avoid spill over effect? Please clarify in the method.

Authors

The details were given in page 8 as follows and we believe these answer the reviewer's question: "Inclusion criteria for study villages for the Intervention were PHC villages in CRR with a population of 200–450. It was felt that such villages, with lay health workers, would be best able to support the programme given the available resources. The 200–450 population criteria per village was decided on 3 grounds: the requirement for a minimum of 20 families with children aged 6-24 months, a population close to the mean village size in CRR (357), and the need to avoid villages that were too large given the size of the team implementing the intervention. Exclusions for the villages were those that were within 5km of already selected villages."

4. I did not find anything related to data analysis in the method section.

Authors

This is a baseline manuscript and not the trial outcome reporting. Statistical analysis is minimal. A section has been added: "Data analysis This article presents the data for the baseline which are analysed using descriptive summaries."

5. My understanding is that, the author precisely describe the intervention design, sample size calculation but what is the primary outcome of interest? I understand there lot to go but little description of outcome parameter would be helpful.

Authors

The authors felt that as this is not a protocol paper the description already given is adequate which is the section at the end of introduction: "The primary objective of the main cRCT trial is to investigate the effects of a complex public health community intervention that sought to improve mothers' weaning-food hygiene practices. We further sought to investigate the effect of the intervention on the level of microbiological contamination in food and water prepared for the child's consumption; and to establish the prevalence of diarrhoea and respiratory symptoms, and diarrhoea admission, as reported by mothers."

6. Intervention team were formed based on literacy, why? Is there any specific rationale? Did they received any training? If so, how long? what is the intensity of the household visit? Can the authors explain a bit more the extent of the training given?

Authors

The intervention were not formed based on literacy – it is simply that the literacy and background of the intervention team are reported as is usually the case in order to indicate the level of expertise used to implement the work. This is an important information for others who may wish to replicate this work and common practice in reporting trial interventions of this type. Their training is already described as much details as needed for a scientific paper and given the limitations of word count, though we are happy to elaborate further.

7. In the table 5, you reported diarrheal and RTI data, but did not found in the result section. Is this ARI or RTI, be consistent throughout the manuscript?

Authors

RTI should be ARI and is a typo error – thank you for pointing this out.

8. In the figure 1, it mentioned that control arm received "use of water in home based gardening campaign", it seems like they will also receive some sort of intervention. Is this active control or passive control? Is there any visit by intervention team? Better to elaborate this control issue in the method section.

Authors

We inserted this detail: "Control villages

After consent by the head of village, and randomisation, the control villages received a 1 day visit by a PHO who using a flip chart during a village gathering talked about using water in household gardening. No further visits were made to the control villages."

PART III

This is a good study attempting to summarise an intervention implementation and baseline data of the first African community-level weaning-food hygiene intervention programme.

COMMENTS

1. The authors should ensure that numbers 1 – 9 are written in words where necessary. Mistakes were made in different places all through the manuscript.

Authors

Thank you. This is now done.

2. Too many keywords. I think 3 – 10 should be enough.

Authors

Thank you. This is now done.

3. Background is too brief. More information is needed on what is known about general food handling practices of mothers of under-5s in the Gambia; and the most prevalent foodborne diseases of under-5s in the Gambia.

Authors

We were limited with journal word count requirements and felt that the back ground was as detailed as needed. Actually there are no other papers than the ones quoted in the one paper reference 10, and our co-author's formative research reported in this paper. Any more details would not be from published reports but anecdotal. We have referenced the thesis that has more formative research data and this will be published in due course. The most prevalent foodborne diseases of under-5s in the Gambia are not known. This is what we entered in page 6-7:

"The Gambia has a high rate of childhood diarrhoea but to our knowledge, there have been no recent studies or interventions of weaning-food in the Gambia. Moreover, our formative research⁹ indicates that the practices and rates of contamination have not changed significantly since 1978.¹⁰

Significantly, we found that weaning-food samples collected immediately after preparation before

feeding to the child, were significantly contaminated with faecal coliform and that this contamination increased after \geq five hours' storage.⁹

There is also the results of the HACCP in table 1.

4. Page 8: "ARI" was not used previously. Write out the abbreviation in full.

Authors

Thank you. This is now done.

5. CRR was 357(SD+59)??? CRR was 357 \pm 59.

Authors

Thank you. This is now done.

6. Of what importance is "a UK epidemiologist" to the study in the randomisation process?

Authors

Randomisation needs to be done outside of the setting of the team (in our case in the Gambia) and therefore being in the UK and an epidemiologist indicates unbiased randomisation and expertise.

7. "...a statistician in the UK"??

Authors

as above.

8. Page 9. Footnote can still be on the same page.

Authors

Thank you. This is now done.

9. Page 10, line 38 "...to all the village..." villages.

Authors

Thank you. This is now done.

10. Page 15, line 29 "The majority of the mothers were farmers and illiterate." Include frequency/percentage

Authors

Thank you. This is now done.

11. Page 15, line 49. "Animations from South Asia were used..." Was any permission needed/obtained to use these materials?

Authors

These are public domain in parts and others were given with permission as the study authors are acknowledged.

12. Page 19, line 8. "PHOs, TCs" abbreviations already known.

Authors

Thank you. This is now done.

13. Both discussion and conclusion lack quantitative data. Kindly include figures (frequencies, percentages, etc.)

Authors

This is common practice. In the author's experience the data are expressed in tables, a number of critical ones are expressed in the results and the discussion will rarely mention data unless for a very particular purpose of comparison etc. The conclusions almost never has data. We followed this informal convention. However, if it is required the word count will be increased since each figure will have to come with some repeated explanation already expressed in the results.

14. Rewrite title of Table 1

Authors

Thank you. This is now done.

15. No need of underlining words in Table 3

Authors

We would have preferred the underlines to help clarity but have removed them based on this comment.

16. The column heading of Table 5 needs to be aligned.

Authors

We have aligned in a way that makes the table easier to read.

17. Table 5: "RTI" What does it mean? Nowhere has this been mentioned in the manuscript.

Authors

It is ARI - Thank you. This is now done.

18. Table 6 may not be necessary. This is subject to the editor's decision.

Authors

This is now removed.

19. I recommend that the statistical analysis of the research be improved.

Authors

Based on another previous comment a section has been added. See above please.

20. The paper requires improvements to the English language within the manuscript before being published.

Authors

It has been worked through. Thank you

VERSION 2 – REVIEW

REVIEWER	Laura Schwab Reese
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	Purdue University, USA
REVIEW RETURNED	04-Jan-2018
GENERAL COMMENTS	The current draft of this manuscript does not require specialist statistical review.
REVIEWER	Dr Irina Chis Ster St George's University of London
REVIEW RETURNED	08-Jan-2018
GENERAL COMMENTS	There were no critical comments to be addressed. As I mentioned in my previous review, I found the manuscript pleasant to read. In the absence of any formal statistical analysis I leave the final decision to the Editor.
REVIEWER	FASORO AYODEJI AKINWANDE AFE BABALOLA UNIVERSITY, NIGERIA
REVIEW RETURNED	12-Jan-2018
GENERAL COMMENTS	I observed that that authors failed to make the previous corrections suggested. I hope they have their justification for doing that. The references need to be worked on for consistency with the Journal's referencing style.

VERSION 2 – AUTHOR RESPONSE

The 6th and 7th comments "Of what importance is "a UK epidemiologist" to the study in the randomisation process? a statistician in the UK"??" were not addressed.

Authors: We did not change this since we believe there was an important quality assurance reason why we employed this method of randomisation. In our response to reviewers we remarks:

6. Of what importance is "a UK epidemiologist" to the study in the randomisation process?

Authors

Randomisation needs to be done outside of the setting of the team (in our case in the Gambia) and therefore being in the UK and an epidemiologist indicates unbiased randomisation and expertise.

7. "...a statistician in the UK"??

Authors:as above.

i.e. in terms of the statistician in the UK, randomisation needs to be done outside of the setting of the team (in our case in the Gambia) and therefore being in the UK and a statistician indicates unbiased randomisation and expertise.

The only other option would be to say a statistician outside of the Gambia. Unless otherwise requested we will keep the text as it is for now.

- The 10th comment I made was "Page 15, line 29 "The majority of the mothers were farmers and illiterate." Include frequency/percentage". I couldn't find that in the revised copy.

Authors: This is done

- The 11th comment was "Page 15, line 49. "Animations from South Asia were used..." Was any permission needed/obtained to use these materials?" The authors did not address this concern

Authors: In our response to reviewers we remarks:

11. Page 15, line 49. "Animations from South Asia were used..." Was any permission needed/obtained to use these materials?

Authors: These are public domain in parts and others were given with permission as the study authors are acknowledged.

We have now inserted this in the manuscript.

- The 15th comment was "No need of underlining words in Table 3". I observed that Table 3 is now Table 2 in the revised copy. However, words were still underlined.

Authors: Underline taken out. Thank you

There were no other comments to address.

- Please remove the 'On-line annex' embedded in your main document and upload it separately in PDF format.

Authors: done now

- Table 2 has been cited but is missing in the main text of your main document, please amend accordingly.

Authors: table 2 is already mentioned at the end of the first paragraph of page 11 stating: " The programme's daily schedule and tools and including their links with the motivational theory, are summarised in Tables 1 and 2."

- We have implemented an additional requirement to all articles to include 'Patient and Public Involvement' statement within the main text of your main document. Please refer below for more information regarding this new instruction:

Authors must include a statement in the methods section of the manuscript under the sub-heading 'Patient and Public Involvement'.

This should provide a brief response to the following questions:

How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?

How did you involve patients in the design of this study?

Were patients involved in the recruitment to and conduct of the study?

How will the results be disseminated to study participants?

For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

Patient advisers should also be thanked in the contributorship statement/acknowledgements.

If patients and or public were not involved please state this.

Authors - above is now done

- Aside from the clean copy, please also provide a marked copy of your manuscript with 'tracked changes' and upload it under the file designation 'marked copy'. This is to show all the changes you have made for your paper.

Authors - above is now done

When you have made these changes, please re-submit the files for consideration. Your paper will be in the queue entitled 'Unsubmitted Manuscripts' (for new submission) or 'Revised Manuscripts in Drafts' (for revised manuscripts) in your Author Centre. Our system will create a unique PDF from any Word documents and image files (jpeg or TIF) that you upload.