**PEER REVIEW HISTORY**

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

**ARTICLE DETAILS**

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| **TITLE (PROVISIONAL)** | Integrating an Early Child Development Intervention into an Existing Primary Health Care platform in Rural Lesotho: A prospective Case Control Study |
| **AUTHORS** | Ndayizigiye, Melino; McBain, Ryan; Whelley, Collin; Lerotholi, Rorisang; Mabathoana, Joalane; Carmona, Merida; Curtain, Joe; Birru, Ermyas; Stulac, Sara; Miller, Ann; Shin, Sonya; Rumaldo, Nancy; Mukherjee, Joia; Nelson, Adrianne |

**VERSION 1 – REVIEW**

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| **REVIEWER** | Catherine Draper<br>University of the Witwatersrand, MRC-Wits DPHRU |
| **REVIEW RETURNED** | 01-Sep-2021 |

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| **GENERAL COMMENTS** | This manuscript reports on important research to promote ECD in a rural African setting. I have minor suggestions to improve the manuscript:<br><br>INTRODUCTION<br>Page 4, line 34: The correct term is low- and middle-income countries (LMICs)<br><br>Page 5, lines 8-50: The second half of this paragraph (from the sentence about the salary for a mental health professional) seems a bit all over the place. Many valid points are being made to contextualise these settings, but they don't pull together to form a cohesive narrative. It also isn't 100% clear if facility is always referring to health facilities, and there is a bit of chopping and changing in terminology – the next paragraph refers to clinics.<br><br>METHODS<br>Page 7, line 12: I presume this I referring to the pilot study in Peru?<br><br>Page 7, line 36-37: Check the grammar of this sentence.<br><br>I would suggest moving the study design to the beginning of the methods, and moving the information about recruitment to the 'study sample' section, and changing this to 'study sample and recruitment'.<br><br>Page 9: I think the information about the intervention should be moved to the 'intervention' section. The training information could also be moved there.<br><br>Information should be provided on the suitability of the Parent Ladder and EASQ for an African setting. I know translation is mentioned, but this doesn't address the contextual relevance of these measures, given that many ECD measures are optimised for |

| | WEIRD settings.<br><br>RESULTS<br>Page 13, lines 15-17: This is a bit confusing – completing the final session means they completed all 18 weeks of sessions? |
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| **REVIEWER** | Nur-E- Salveen<br>Maternal and Child Health Division (MCHD) |
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| **REVIEW RETURNED** | 22-Nov-2021 |

| **GENERAL COMMENTS** | Study design is not clear to me. As mentioned it was prospective case control study, need to more describe on it and also the background of cohort sample.<br>Method: Need to clarify about trainer and trainee information, how many batches had been conducted, trainee's number in a batch, training duration for each batch. Was only one ECD nurse responsible for conducting group session for 130 mothers?<br>Intervention procedure need to write in elaborate as if any body can repeat the program. Using a flow chart of study process would be visible at a glance. It was not easy to understand what the procedure was going on. The curriculum of intervention must be concise about its content such as toys/topics according to age. Was the curriculum Re translated? How many mothers attended per session at clinic. Monitoring and Evaluation part was limited.<br>If the intervention was for 6 months and children enrolled 0 to 2 months then children would be assessed at 7 to 9 months. So mentioned 7 to 11 months not cleared. Baseline, midline, and endline period should be mentioned as age clearly for both intervention and control group.<br>Is there any difference between baseline, midline and endline within intervention group? |
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**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1
Dr. Catherine Draper, University of the Witwatersrand
Comments to the Author:
This manuscript reports on important research to promote ECD in a rural African setting. I have minor suggestions to improve the manuscript:

INTRODUCTION
Page 4, line 34: The correct term is low- and middle-income countries (LMICs)

*Thank you, we have made this correction.*

Page 5, lines 8-50: The second half of this paragraph (from the sentence about the salary for a mental health professional) seems a bit all over the place. Many valid points are being made to contextualise these settings, but they don't pull together to form a cohesive narrative.

*Yes, we agree this needed to be modified. We have made edits to improve the flow of these paragraphs and better frame our study, including re-ordering some sentences and re-writing others.*

It also isn't 100% clear if facility is always referring to health facilities, and there is a bit of chopping and changing in terminology – the next paragraph refers to clinics.

*Thank you for pointing out this inconsistency. We have changed all references to "health facility" to "clinic".*

METHODS

Page 7, line 12: I presume this I referring to the pilot study in Peru?

*Thank you for this query. This refers to the adaptation from the CASITA intervention in Peru to the Lesothoan pilot we describe here. We have included some clarifying terms in that sentence.*

Page 7, line 36-37: Check the grammar of this sentence.

*We have changed the word "through" to "at" and "may respond to patients questions" to "will be invited to respond to patients' questions".*

I would suggest moving the study design to the beginning of the methods, and moving the information about recruitment to the 'study sample' section, and changing this to 'study sample and recruitment'.

*We agree this is clearer and have made the changes, thank you for the suggestion.*

Page 9: I think the information about the intervention should be moved to the 'intervention' section. The training information could also be moved there.

*Thank you, we have done so.*

Information should be provided on the suitability of the Parent Ladder and EASQ for an African setting. I know translation is mentioned, but this doesn't address the contextual relevance of these measures, given that many ECD measures are optimised for WEIRD settings.

*Thank you for this comment. We have included information about the use of the ASQ with consistent findings to other international settings in similar samples in South Africa and Zambia. The Parent Ladder has not been used in similar African settings, and we included this information in the limitation section.*

RESULTS

Page 13, lines 15-17: This is a bit confusing – completing the final session means they completed all 18 weeks of sessions?

*That is correct, 100% completed 14 weeks and 70% completed all 18 weeks. We included in analysis those that completed at least 14 weeks. We have edited this paragraph as follows:*

*“Of the 119 intervention dyads, 100% completed 14 weeks and 83 (70%) completed all 18 weeks. All those completing 14 sessions were included in final analysis, with the exception of one twin who was removed to prevent family bias. In the end, 243 participants had final outcome data.”*

**Reviewer: 2**
**Ms. Nur-E- Salveen**

Comments to the Author:

Study design is not clear to me. As mentioned, it was prospective case control study, need to describe more on it and also the background of cohort sample.

*Thank you for this comment.*

*With respect to the study design, we employed a hybrid cohort study design, in which we selected participants based on their exposure to the intervention. The study is a hybrid with respect to prospective and retrospective components. From the vantage point of intervention enrollees, the study represents a prospective cohort design, in which we observed the probability of ECD outcomes looking forward. From the vantage point of the comparison group, the study represents a retrospective cohort design, in which we observed the probability of ECD outcomes looking backwards.*

*We have added a paragraph in the results section describing the sample.*

Method: Need to clarify about trainer and trainee information, how many batches had been conducted, trainee's number in a batch, training duration for each batch.

*Thank you for pointing this out. We added to the training section of the text, including the following: 80 VHWs attended each monthly refresher training and there were four monthly sessions of approximately three hours during the course of the 18-week program. “During this meeting, all 80 VHWs practiced delivering home sessions for which they received feedback and an opportunity to clarify questions arising in the field. The ECD nurse also reviewed the home visiting agenda and focused on problem areas observed during her fidelity visits.”*

Was only one ECD nurse responsible for conducting group session for 130 mothers?

*Yes, one ECD nurse conducted all group sessions. They were spread out over several months and each group was small (4-6 dyads).*

Intervention procedures need to write in, elaborate as if anybody can repeat the program. Using a flow chart of study process would be visible at a glance. It was not easy to understand what the procedure was going on. The curriculum of intervention must be concise about its content such as toys/topics according to age. Was the curriculum Re translated?

*Thank you for this comment. We agree more information on the curriculum would be useful. We have included the group and home session curriculum guide as a tables 4a and 4b.*

*We did not back translate the curriculum, however, it was translated by a professional translator and then reviewed by both the ECD Nurse and Maternal Child Health Program Manager.*

How many mothers attended per session at clinic?

*Thank you for this comment, 4-6 dyads attended each session. We have included this information in the manuscript.*

Monitoring and Evaluation part was limited.

*Yes, we added more information about the fidelity checks for data collection and intervention:*

*Data collection: "Data were collected on tablets and site supervisors attended 10% of data collection events in which they completed the assessment simultaneously and discussed discrepancies with the data collector. Changes were made and the site supervisor recorded discordant questions as a percent. Follow-up training was done if 20% or more questions were discordant."*

*Intervention: "The ECD nurse conducted unannounced spot checks of VHWs to ensure they were conducting the intervention as intended. An assessment form was completed by the ECD nurse indicating whether each activity was completed as intended. She met with the VHW after the visit and reviewed the assessment. VHWs were given an additional individual training session if one part of the session was not completed accurately."*

If the intervention was for 6 months and children enrolled 0 to 2 months, then children would be assessed at 7 to 9 months. So mentioned 7 to 11 months not cleared. Baseline, midline, and endline period should be mentioned as age clearly for both intervention and control group.

*Some of the children received their child assessment later than they were assigned to due to logistical considerations such as delayed clinical travel time, scheduling, and missed clinical appointments.*

*Therefore, the average follow-up time was 8 months and the mean ages between the cohorts were 0.1 months.*

Is there any difference between baseline, midline and endline within intervention group?

*We do not have that information. We did not design the study to look at change within the intervention group and the study is not powered to detect that change. Rather, it was designed to compare the intervention and control groups at one timepoint. We respectfully ask to maintain our original analysis as designed.*

**VERSION 2 – REVIEW**

| **REVIEWER** | Catherine Draper<br>University of the Witwatersrand, MRC-Wits DPHRU |
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| **REVIEW RETURNED** | 10-Jan-2022 |

| **GENERAL COMMENTS** | I am happy with how the authors have responded to my suggestions. |
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