PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	CASITA: A controlled pilot study of community-based family coaching to stimulate early child development in Lima, Peru
AUTHORS	Nelson, A. Katrina; Miller, Ann; Munoz, Maribel; Rumaldo, Nancy; Kammerer, Betsy; Vibbert, Martha; Lundy, Shannon; Sopapulco, Guadalupe; Lecca, Leonid; Condeso, Alicia; Valdivia, Yesica; Atwood, Sidney; Shin, Sonya

VERSION 1 – REVIEW

REVIEWER	Emmanouil Bagkeris Institution and Country University College London Competing interests: No competing interests
REVIEW RETURNED	06-Mar-2018

GENERAL COMMENTS	1. In the conclusion of the abstract please be more specific regarding the domains that improved after the intervention. 2. Did you perform a sensitivity analysis to identify differences between the modes of CASITA delivery? Please conduct this sensitivity analysis and report the results briefly at the results section. The individuals from the one-on-one CHW arm may perform better. 3. Please specify what test was performed to identify differences of the baseline covariates between intervention and control arms. 4. What kind of regression was used? Please be more explicit at the Analysis section. 5. In table 1, please add a column with p-values and in footnotes specify the test(s) used to obtain the p-values. 6. Perhaps consider adding the small sample size as a limitation of the study at the discussion section. 7. In table 2 please remove the vertical lines and consider splitting the table into 2 (EASQ and internal EASQ) and flip the table in landscape format.

REVIEWER	Sarah Carsley Institution and Country Public Health Ontario, Canada Competing interests None to declare
REVIEW RETURNED	07-Mar-2018

GENERAL COMMENTS	This study examined a community-based early-stimulation coaching and social support intervention “CASITA” on early childhood development outcomes in an urban poverty setting.

	This was a pilot non-randomized controlled trial to establish proof-of-concept in the particular resource limited setting in a district in Lima, Peru. The intervention involved 12 weekly sessions with a community-health worker, either in a group format at a community centre or health post, or individual sessions at the participating child-mother dyad's home. The control group was given monthly nutritional support only. Child development outcomes improved in all the domains of the Extended Ages and Stages Questionnaire (EASQ) for the intervention group, and not in the control group. Other outcomes measures also showed improvements. This is an important area of work, where research is needed especially in resource limited settings. Interventions to promote early childhood development are often resource intensive and costly, so this pilot proof-of-concept study aimed at delivering low-cost interventions is vital. The authors did a nice job of concisely describing this pilot study and used appropriate statistical methods to answer the research question. However, there needs to be more clarity about how the intervention and control groups were chosen, since they were not randomized. I would have liked to see more discussion of future steps. For example, will the authors try and keep following the dyads to determine the effectiveness of the intervention on longer-term outcomes? Will this pilot be scaled up into a full randomized controlled trial? Specific Comments Abstract In the Participants section, starting the sentence with 60/128 was confusing. This is a result, so should be in the results section. The acronym EEDP should be spelled out the first time, or since it is in a different language can say "validated developmental delay tool." Methods The estimated prevalence of children at risk for delay was estimated at 50-70% but this reference was in children living with HIV. Do the authors have any data about the estimated prevalence in their study population? In the Intervention section, describing the reason why individual and group modalities were combined would be helpful for the reader (I believe it is because of sample size). It comes later as a limitation of the study, but would be beneficial earlier. How many urban and rural health posts were there? The description of how the intervention and control groups were allocated is confusing because the word 'randomly' is used often, but in the flow chart (Figure 2) it says "not randomized" and the unit of allocation is unclear (individual or health post). Because there are individuals within health posts, and certain health posts are providing different versions of the intervention, more clarity about how the intervention and control groups were decided would be beneficial. Especially since there was no randomization, this would be a potential source of bias. From the sentence "randomly allocated (ratio 1:2)", I inferred the dyad was the unit of allocation. However, in the discussion the authors mention they did not randomize at the level of the individual. As well, what was the rationale for a 1:2 ratio rather than equal groups?

	Discussion Good discussion of where this study fits in past literature and limitations. Since this was a proof-of-concept study I would have liked to see a bit more of a discussion about the opportunities/challenges of this intervention in this setting and possibility of scaling up to a larger randomized controlled trial.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

We thank the reviewers and editors for their careful examination of our manuscript, and appreciate the opportunity to improve it based on their suggestions. Our responses to comments are in red below the individual questions.

Comments to the Author

1. In the conclusion of the abstract please be more specific regarding the domains that improved after the intervention.

A: We thank the reviewer for this suggestion. The sentence in the conclusion section of the abstract now reads as follows: “An evidence-based early intervention delivered weekly during 3 months by a community health worker significantly improved children’s communication, motor and personal/social development in this proof-of-concept study.”

2. Did you perform a sensitivity analysis to identify differences between the modes of CASITA delivery? Please conduct this sensitivity analysis and report the results briefly at the results section. The individuals from the one-on-one CHW arm may perform better.

A: Although we did not conduct a formal sensitivity analysis, we did do a comparison of the 2 intervention modes, which we had mentioned in the discussion section as follows: “of note, outcomes did not differ significantly between individual and group study arms.“. We thank the reviewer for the suggestion to address this more broadly, but we believe that because of the very small numbers in this pilot study, we are very underpowered to look at those differences. Although perhaps any statistically significant differences might have been informative, we cannot tell whether the fact that there weren’t was simply a power issue or no actual difference. It could be misleading for us to address it more substantially. However, if the reviewer strongly disagrees, we can add something like the following sentence to the results section:
“Outcomes did not differ significantly between individual and group study arms, however this study was not powered to detect a difference between these groups.”

3. Please specify what test was performed to identify differences of the baseline covariates between intervention and control arms.

4. What kind of regression was used? Please be more explicit at the Analysis section.

A: We have altered the analysis section to read as follows, and hope that this addresses the reviewer’s concerns in both 3 and 4:

"Two-by-two tables using chi square or Wilcoxon rank sum, t-tests and univariable and multivariable logistic and linear regressions were conducted for binary and continuous baseline covariates and outcomes respectively (using robust standard errors to account for clustering by district for outcomes)."

5. In table 1, please add a column with p-values and in footnotes specify the test(s) used to obtain the p-values.

A: We thank the reviewer for this suggestion. Although we usually limit p values to inferential statistics rather than descriptive, we have added this column to the table as requested.

6. Perhaps consider adding the small sample size as a limitation of the study at the discussion section.

A: We have changed a sentence in the discussion section on limitations to read as follows:
Because of resource constraints, our sample size is small; we did not conduct a priori power calculations and did not randomize at the level of the individual.

7. In table 2 please remove the vertical lines and consider splitting the table into 2 (EASQ and internal EASQ) and flip the table in landscape format.

A: We have done as requested.

Reviewer: 2

Comments to the Author
Summary and General Comments
This study examined a community-based early-stimulation coaching and social support intervention "CASITA" on early childhood development outcomes in an urban poverty setting. This was a pilot non-randomized controlled trial to establish proof-of-concept in the particular resource limited setting in a district in Lima, Peru. The intervention involved 12 weekly sessions with a community-health worker, either in a group format at a community centre or health post, or individual sessions at the participating child-mother dyad's home. The control group was given monthly nutritional support only. Child development outcomes improved in all the domains of the Extended Ages and Stages Questionnaire (EASQ) for the intervention group, and not in the control group. Other outcomes measures also showed improvements. This is an important area of work, where research is needed especially in resource limited settings. Interventions to promote early childhood development are often resource intensive and costly, so this pilot proof-of-concept study aimed at delivering low-cost interventions is vital.

The authors did a nice job of concisely describing this pilot study and used appropriate statistical methods to answer the research question. However, there needs to be more clarity about how the intervention and control groups were chosen, since they were not randomized.
I would have liked to see more discussion of future steps. For example, will the authors try and keep following the dyads to determine the effectiveness of the intervention on longer-term outcomes? Will this pilot be scaled up into a full randomized controlled trial?

Specific Comments
Abstract
In the Participants section, starting the sentence with 60/128 was confusing. This is a result, so should be in the results section. The acronym EEDP should be spelled out the first time, or since it is in a different language can say "validated developmental delay tool."

A: We thank the reviewer for this suggestion. We have removed the “60/128” and replaced EEDP with “validated developmental delay tool”.

Methods
The estimated prevalence of children at risk for delay was estimated at 50-70% but this reference was in children living with HIV. Do the authors have any data about the estimated prevalence in their study population?

A: We thank the reviewer for this question. Unfortunately, these were the only prevalence estimates that were available to us. We agree that the statement about prevalence estimates is unnecessary here and have deleted it.

In the Intervention section, describing the reason why individual and group modalities were combined would be helpful for the reader (I believe it is because of sample size). It comes later as a limitation of the study, but would be beneficial earlier.

A: We have added the following text to the analysis section as follows: “Budgetary constraints limited enrollment sample size to 60 dyads; children were screened until 60 eligible dyads were enrolled. Group and individual intervention arms were analyzed together as “intervention” to increase statistical power.”

How many urban and rural health posts were there?

A: Two rural and four urban health posts were included. We have included these numbers in the Study Populatin section.

The description of how the intervention and control groups were allocated is confusing because the word ‘randomly’ is used often, but in the flow chart (Figure 2) it says “not randomized” and the unit of allocation is unclear (individual or health post). Because there are individuals within health posts, and certain health posts are providing different versions of the intervention, more clarity about how the intervention and control groups were decided would be beneficial. Especially since there was no randomization, this would be a potential source of bias. From the sentence “randomly allocated (ratio 1:2)”, I inferred the dyad was the unit of allocation. However, in the discussion the authors mention they did not randomize at the level of the individual. As well, what was the rationale for a 1:2 ratio rather than equal groups?

A: We apologize for the confusion. We randomized the 6 health posts to one of 3 arms (control, group and individual intervention), of which 2 were lumped into one category (intervention) for analysis. We have changed the sentences in the methods section to read as follows, which we hope is clearer:
“We stratified health posts by urban (n=4) versus rural (n=2), then randomly allocated health posts(ratio 1:2) to receive either monthly nutritional support alone (control) or CASITA and monthly nutritional support (group intervention, individual intervention). Participants’ study arm was based on the assignment of their local health post.”

We have also revised the text in the discussion section to highlight the possibility of bias.
“Because of resource constraints, our sample size is small; we did not conduct a priori power calculations and did not randomize at the level of the individual. Although we used robust standard errors during regression to mitigate the possible effects of clustering at the clinic level, it is possible that non-independence may have biased our results.”

Discussion

Good discussion of where this study fits in past literature and limitations. Since this was a proof-of-concept study I would have liked to see a bit more of a discussion about the opportunities/challenges of this intervention in this setting and possibility of scaling up to a larger randomized controlled trial.

A: We thank the reviewer for this comment! Our constraint here was the word limit. We have received funding to expand CASITA to 3000 children in Carabayllo and currently have an RCT underway. We hope that the results from that project will be informative in the ways the reviewer mentions. We have altered the discussion text to reflect that as follows:

“Expansion to all of Caraballyo is underway, including screening of 6000 children and a randomized controlled trial of more than 350 children. This larger research study will, we hope, determine how effective and cost-effective CASITA is at scale and over longer periods of time.”

Correction: *CASITA: a controlled pilot study of community-based family coaching to stimulate early child development in Lima, Peru*

Nelson AK, Miller AC, Munoz M, *et al*. CASITA: a controlled pilot study of community-based family coaching to stimulate early child development in Lima, Peru. *BMJ Paediatrics Open* 2018;2:e000268. doi: 10.1136/bmjpo-2018-000268.

The first author's first name, Adrianne was spelled incorrectly as 'Adrienne' in the published version.

BMJ Paediatrics Open 2018;**2**:e000268corr1. doi:10.1136/bmjpo-2018-000268corr1