Reviewer’s report

Title: Effects of home-based play-assisted stimulation on developmental performances of children living in extreme poverty: a randomized single-blind controlled trial

Version: 0 Date: 24 Apr 2017

Reviewer: Robert Bandsma

Reviewer's report:

The study by Worku et al., focuses on an important health problem. The study is relevant and design reasonable.

I have the following comments.

General comments

Check grammar and spelling throughout the paper; for example:

"computer-generated"

"enriching caregiving practices [has] been confirmed"

"n: 39"

Explain what is meant by play/stimulation interventions early in the paper. Also, keep terminology consistent, as it is confusing with play-assisted stimulation, psychosocial stimulation, etc. being used in the paper.

Support statements, especially very strong statements, with evidence.

Provide some insight as to what the situation is like for children living in foster care, and how this might differ from other children in the same region in a "typical" home setting. How does this influence development? How is care different? Also, what is the SOS village?

Explain what makes the Denver II-Jimma different from the Denver II?

Abstract

Line 14 This is a strong statement, "Children living with foster families in a resource-limited context such as in Ethiopia have developmental problems." Do authors mean these children are at risk for developmental problems? Could authors give a brief explanation or example of why these children are at risk?
Line 37 "Significant intervention effects are found…" Clinically or statistically? Add statistics to show that results are significant.

Abstract Methods: frequency, duration of the intervention not mentioned. Age range of the children? Main outcome assessed when?

Line 41: "protection" unclear what is meant here.

Abstract Results: use past tense consistently throughout this section.

Line 60"…benefits are already observed for the children in the intervention group." Can this be explained? Again, also add statistics.

Background

Page 2 Line 35 "The main reason is that extreme poverty is strongly linked to undernutrition, poor sanitation, poor maternal education, increased maternal stress and depression, restricted learning opportunities and inadequate stimulation at home." Explain the association between extreme poverty, these factors listed, and child development.

Line 44 "For instance, enriching caregiving practices have been confirmed to improve cognitive and social emotional development in children under five." In all children under five? Explain the population and where this has been shown to be effective.

Line 47 "Responsive stimulation delivered at home improves child development and care even after the intervention was ended. It also enhances parenting behaviors." Isn't it the case that parenting behaviours are the mechanism in which care is improved and child development is therefore improved? This last sentence seems superfluous.

Line 51 "Such interventions are effective, especially, when they are of high quality, organized at home and involve the parents." What is the evidence behind these points? Add reference(s). Also, is there actually evidence behind interventions organized at home being more effective than those conducted elsewhere? Is this dependent on the circumstances?

Page 3, line 12. "demonstrations has significantly improved" remove " has".

Page 3 Line 37 "Wider age-ranges and holistic developmental outcomes (social-emotional, personal-social, language, fine and gross motor), all together, have not been investigated. Only cognitive or motor or language or social-emotional skills, for example, or two skills in combination, of children from 12-24 months or 6-35 months, or less than two years of age have
been considered in previous studies." In all populations or just in children in foster care? Also add references to these statements.

Page 4. Line 1 "If the poorest and most marginalized children and families are supported early in life with play-based interventions, the cycle of poverty may be interrupted, sustainable development ensured, and developmental outcomes of the children improved." How exactly? add sentence to make this a little clearer.

Line 22-24 ".recovery of mainly social emotional and language skills" . Please do not use the word recovery unless you can demonstrate there were clear baseline deficits in skills compared to a reference population.

Methods

Page 5, line 3-5 " having severe or profound intellectual disabilities." How was this determined?

Line 15 "… difference of 0.09 (SD: 0.13) …" What exactly does this mean? Why was this chosen for your sample size calculation? More detail is required.

Line 41 "The blinding was evaluated to be successful." How?

Line 43 "Children in the intervention group received home-based play-assisted stimulation in addition to the basic services provided to children in both groups." There isn't a strong description of what exactly was done. A description of personnel and materials is there, but there isn't enough detail otherwise. Also, the intervention should be introduced earlier in the paper.

Page 6 Line 41 "It has an excellent inter-rater and test-retest reliability." Is there a reference with data supporting this?

Page 7 Line 12 This reference is cited: WHO Expert Committee: Physical Status: the Use and Interpretation of Anthropometry. In. Geneva, Switzerland; 1995, but it is outdated.

Page 8 Line 1 "Each child was assessed three times during the study period: at baseline, after three months (midline) and after six months (endline)." This should be explained much earlier. What is the reason for assessments at these time points?

Line 27 "…normal distribution was assumed for the analysis." Is this appropriate? What is this assumption based on?
Results

As stated before, I would consistently use the past tense.

Line 3 "A total of 78 children were randomized into intervention and control groups." Was the sample size calculation and the number recruited actually the exact same? Also, mention the number of children that were screened.

Line 22 "Significant differences were observed in birth order and maternal age." Add more detailed description. Why were these differences seen? How do they influence the results? These aspects should be discussed in the discussion section.

Line 5 "For language (at midline: $\beta = 1.46$, $Z = 2.43$, $p = 0.0151$, effect size (ES) = 0.34; at endline: $\beta = 1.79$, $Z = 3.20$, $p = 0.0014$, ES = 0.55), and social-emotional (at midline: $\beta = -12.73$, $Z = -4.07$, $p < 0.0001$, ES = -0.603; at endline: $\beta = -27.06$, $Z = -11.61$, $p < 0.0001$, ES = -1.28) performances, children in the intervention group have higher average performance scores than children in the control group, both at midline and endline; hence, the benefit of the play-assisted developmental intervention is already observed after three months." This is a very long and confusing sentence. Please break up into shorter sentences.

Line 27 "At the end of the study, most mothers said they have observed encouraging developmental improvements in their children." What percentage? What were they actually asked, and was this through a questionnaire, qualitative interviews, etc.? If not systematically assessed in a standardized fashion, you can mention it in the discussion but then it does not belong in the results section.

Figure 1 Why didn't the four excluded children meet criteria?

Discussion

Make the discussion more structured; it is difficult to read because it is not a natural flow from point to point.

A much more thorough discussion of the development assessment tools used and validity and limitations in LMIC's is needed. See for example Gladstone et al., Arch Dis Child. 2008

Line 27

"We observed that families with lower income benefited more from the intervention. Evidence of this kind has already been documented." What is the reason for this? And in what studies/settings have it been documented?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal