Reviewer's report

**Title:** Effect of nutritional supplementation of breastfeeding HIV positive mothers on maternal and child health: findings from a randomized controlled clinical trial

**Version:** 1  **Date:** 10 August 2011

**Reviewer:** marzia lazzerini

**Reviewer's report:**

The article is very interesting.

The following are all minor essentials revisions.

1. Introduction, first sentence on mean milk production and energy requirements: I suggest to report a range of values rather than a point estimate (instead than 749 g/day and 626 kCal/day use ranges). Add a reference on international guidelines for nutrition in breastfeeding women, rather than an article.

2. Introduction, page 4, line 3 to 6 “This can normally be mobilized from their stores at a rate of 172 kcal/day. However mothers with low reserves or diseases with additional metabolic demands like TB or HIV during pregnancy need to compensate by increasing their daily energy consumption.”: this two sentences are unclear. Does it mean that generally mothers do not need an energy supplement, and that only HIV and TB mothers need supplemental energy during BF in developing countries? I suggest to clarify these sentences and to add some more references on the debate on whether ALL breastfeeding mothers need a supplement or not (there are different indications in literature). I would also mention the level of the food security of the population, their physical activity (most of them are workers and go back to work early) and if this mothers have any access to food supplement during pregnancy. Also, comment on the amount of energy provided by the intervention (280kcal) in comparison with expected energy needs.

3. Introduction, page 4, Add a sentence on expected weigh lost during breastfeeding. There is a lot of literature on this, well-nourished women are reported to lose an average of 500-800 g per month for the first six months of breastfeeding (Butte and Hopkinson 1998); under-nourished women are reported to lose, on average, about 100 g per month (Butte and Hopkinson 1998). Also, considered the expected weigh lost in comparison with the observed results when commenting the results of the study.

4. Introduction, page 4, line 8: a full point is missing before “we tested…”.

5. Introduction, page 5 line 5-6 “Mothers whose infants tested HIV negative were counseled on either discontinuing breastfeeding at 6 months, or heat-treating expressed breast milk”: do you mean “infants tested HIV positive (rather than negative)? Or do you mean “tested HIV negative at 6 weeks” or what else?
6. Introduction, page 5 line 4-6: I suggest to move these two sentences in the methods sections.

7. Methods, page 5: from the registered protocol the supplement is called “Sibusiso ready food supplement”. This may be added also in the article. I also suggest to add a table with the nutritional content of the supplement (or either specify in the text).

8. Methods, page 5, last line “study numbers”: I suggest to modify in “study identification numbers”.

9. Methods, page 5, regarding randomisation, blinding and contamination/dilution: I suggest to describe these procedures in order, starting from randomisation, then blinding, then dilution/contamination. Also I suggest to move here a couple of sentences that are now of page 7 and 8, and to make explicit who where the outcome assessors. This part could be reordered more or less as follow “Randomisation took place by mothers removing a card pre-marked with group number from a slit in a closed box; this was done to enable them to be confident that the randomisation was unbiased. Randomised was done by a study counsellors who maintained a separate record of the randomisation log. Outcomes were assessed by a separate clinicians (note: verify is this is correct). To ensure that the clinician was blinded, the counsellors issued a brown bag containing either the nutritional supplement or the non-nutritive supplies. Both supplement and the non-nutritive supplies had identical appearance.” The sentences on dilution/contamination could either follow here, or go at the end of the chapter, on page 8. “To prevent dilution of the effect of the intervention and mothers discussing the content of their brown bags, separate clinic visit days were allocated for the two groups. To monitor adherence, a monthly register with mothers’ signatures was maintained as well as a questionnaire was administered to the mothers at every visit discussing daily intake of the supplement and any possible reasons for not taking the supplement including information on any benefits or side-effects that they attributed to the supplement. The counselors also tried to ascertain that the mothers were not sharing the supplement with members of their household.”

10. “The counselors also tried to ascertain that the mothers were not sharing the supplement with members of their household.” Add how this was done, if by interview or by direct observation. In the result session, report the results on this point (sharing practices).

11. Methods, page 6, first two sentences “To calculate the sample size, the null hypothesis proposed that the difference between the mean LBM in the breastfeeding control and breastfeeding supplemented groups would be less than or equal to 4 kg. The alternate hypothesis was that the difference would be more than 4 kg”: I suggest to simplify these two sentences in only one sentence, and make clear for the reader (not all are experts in statistics, and the sentence on the null hypothesis may be difficult to read), that the study was designed to detect a difference of > 4kg.
12. Methods, page 6, line 4, power of the study: why is this 91%? Usually it is either 80 or 90%. Why exactly 91%?

13. Methods, page 6, line 5 “The true difference between the means was assumed to be 0.00”: Is this correct?

14. Methods, page 6, line 6 “The data are drawn from populations with standard deviations of 6.70 and 3.60”: please clarify this sentence.

15. Methods, page 7, Karnofsky score: specify for the reader what this score is for.

16. Methods, page 7 “When indicated they were started on ART”: specify what indication was followed. Specify if that was the WHO recommendations, a local adoption, or else.

17. Methods, page 9 “As low BMI is considered to be an important prognostic marker for breastfeeding HIV positive women.” What is the BMI cut-off which proved to have prognostic value? Is your cut-off (BMI < 25) an adequate cut-off, or should you go for a lower cut-off?

18. Results, page 10, line 19: remove a full point after “supplement”

19. Results, on dietary intake: how was the dietary intake, adequate to the needs or not?

20. Results, page 11, line 9 “In mothers with BMI # 24.9 kg/m2; no significant effect of the supplementation was seen except in LBM where the supplemented group had a significantly lower loss in LBM (0.098 kg) compared to the control group” : ..”: substitute the semi-comma with a comma (after “In mothers with BMI # 24.9 kg/m2.2). The value of LBM is different from what reported in table 3, what value is it?

21. Results: add a table with children characteristics at baseline.

22. Results: table 1: why some continuous measures are reported as mean and SD, and others as mean and IQR?

23. In the discussion I suggest to add some comments on the following points:
   a) The major finding of the study to me is low acceptability of the food supplement. This is a major finding which well sustains the debate on what types of intervention should be prioritised. Comment with reference on other acceptability studies in other regions.
   b) Intensity of the intervention: may it be that calories are not enough to make a difference of 4 kg? Any locally acceptable and cheap food that could be further studied?
   c) Nutritional state of the population. Comment on BMI range of values among mothers. The mean BMI and the IQR are quite high. Was any mother underweight? Any difference in results if a BMI cut-off of 20 is taken instead than
25?
d) Comment on dietary intake in the population (see point 19)

24. Discussion, very last sentence: remove a full point.

25. Abbreviations: if the abbreviation list is requested by the journal, add the full list (not only HIV).

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
'I declare that I have no competing interests’