Reviewer’s report

Title: Adolescent coordinated transition (ACT) to improve health outcomes among young people living with HIV in Nigeria: study protocol for a randomized controlled trial

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Reviewer: Chang Larry

Reviewer's report:

This study addresses an important public health problem, the transition of adolescents from pediatric to adult HIV care. Overall, this protocol is generally well written. My main concern is that the sample size does not seem plausible. Comments are as follows:

1. Study Objectives and Hypotheses-The primary outcome should probably be stated here up front rather than just saying one is evaluating the effectiveness of the intervention. Also, would have your primary outcome only as your #1 hypothesis and everything else in your #2 hypothesis.

2. Randomization-could use more details on actual randomization methods (see CONSORT extension to CRCT section on randomization)

3. Study Population-not sure why you would include individuals who might not transition during the study period, e.g persons age 13.

4. Intervention Description-not exactly clear whether the OSG will continue after 12 month transition, same for case management team.

5. Data Collection-Is viral load routinely done in Nigeria? Will results be returned to participants and their providers?

6. Primary outcome-the composite outcome for retention is a bit worrisome and seems overly complicated. Why not just pick one, relatively standard outcome for retention?

7. Sample Size Calculations-I suspect that the sample size calculations are optimistic and that it would be preferable to enroll a significantly larger number of participants. Was matching accounted for in the calculations? What are the expected intervention and
control arm rates for the primary outcome? Drawing inferences from only 216 participants, of whom only 108 will receive the intervention, across all of Nigeria, when there are 200,000 ALHIV in Nigeria will be challenging, and I suspect many will be skeptical of generalizability. I would refer you to Hayes and Moulton's textbook on CRCTs and the chapter on samples size/power.

8. "Hybrid" design-while the authors indicate they are using a hybrid design, there is not much in the protocol on what implementation indicators they will be tracking, e.g. are OSG's formed as desired, OSG attendance, etc. Might want to consider a framework such as RE-AIM to guide this inquiry.

9. Discussion-a section on study limitations would be helpful

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