Author’s response to reviews

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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Response to Reviewers

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Trials Manuscript TRLS-D-17-00497: Adolescent Coordinated Transition (ACT) to Improve Health Outcomes among Young People Living with HIV in Nigeria: Protocol for a Cluster Randomized Controlled Trial
Dear Trials Editor and Reviewers, thank you for the helpful feedback on our manuscript. Please see below our point-by-point responses.

Reviewer #1: The authors have addressed all the queries satisfactorily. The manuscript needs structural edits and language corrections. Response: A thorough manuscript review with revisions and corrections has been performed, with attention to format, grammar and syntax.

Reviewer #2:

1. The authors have done an acceptable job of responding to comments. I would probably still recommend a statistician double check the sample size/power calculations. Response: As previously noted, the sample size calculation is based on many assumptions, such as the cluster design aspects of the research, the geographic complexity of the working environment, the availability of participants for recruitment at target facilities, and the potential for loss-to-follow-up particularly in this population. The desired effect-size difference, repeated-measures correlations, and cluster intra-class correlations are based on assumptions that seem logical and are driven by previous research in this area. Further, extra care was taken to assess potential loss estimates based on the literature and on knowledge of work with this population. Under these assumptions the sample-size estimates are correct. Violation of any of these assumptions can happen and could result in reduced post-hoc power; however, we will make every attempt to ameliorate this using accepted protocols and sampling strategies. Sample size and power calculations were reviewed by a biostatistician and deemed to be calculated appropriately based on the assumptions presented.

2. One persistent point confusion for me is whether the primary outcome is retention at 12 months, at 24 months (2 primary outcomes), or at 12 months AND at 24 months (one composite primary outcome). Otherwise, I have no further comments currently. Response: Our interest is to develop and evaluate an intervention that provides for long-term retention in care. To that end, we will evaluate retention at two time points (12 months and 24 months). This will allow for a measure of "short-term" retention in care and "long-term" retention in care. It is not anticipated that long-term retention can be met, per se, in those without
short-term retention. In other words, evaluation of this outcome is necessary at two distinct time points. Hence, there are two primary outcome measures (12 months and 24 months), with the long-term retention measurement necessarily a "composite" of those who already demonstrated short-term retention. It is possible that loss-to-follow-up occurs at 12 months but then a patient is recovered for the 24-month evaluation, though it is unlikely this would encompass a large number of patients. Clarifications based on the above have been used to update the Sample Size Estimation narrative in the manuscript, lines 326 to 328, Page 15.