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 Editor,

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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 Editor,

Thank you for your helpful feedback on our manuscript. Please see our response.

Editorial comment: The authors will use two primary outcomes to measure the effect of the intervention. One at 12 months and the other at 24 months with the same subjects. The authors should take into account the multiplicity of tests and thus adapt the analyzes. Several methods exist for taking into account multiple testing. Indeed, authors not stated if the p value for significance will be adapted. Usually, if not multiple testing, p value = 0.05. In the case of multiple testing, P value should be different (lower).

Response: We wish to thank the Editor for carefully reviewing our statistical methodology. Here we provide a response to the inquiry.

We will, in fact, but using p-values in our analyses. We have specified in two locations that we will use both a model and an RM-ANOVA, both of which will not require direct adjustment. However, analyses of changes in percentages could lead to inflated Type 1 error, and so we have added a new sentence to explicate our plan more fully.

Line 381 - The manuscript states that Poisson models with a time offset will be explored. This allows for testing a purported predictor variable (time) directly as an indicator of change, which does not require an offset for multiple testing since it simply tests for significance of time as a factor.

Line 401 - The manuscript states that repeated-measures analyses will be used, which indirectly addresses this inquiry because that analysis is specifically designed to test the same subjects over time without inflating Type 1 error rates.

The following sentence was added in line 401: Owing to multiple tests among the same subjects, an approximate Type 1 error of .05 will be maintained either directly through the use of a
technique designed to accommodate repeated-measures designs (e.g., RM-ANOVA), or through the use of post-hoc adjustment of p-values (e.g., Bonferroni’s Method).