Author's response to reviews

Title: The Cameroon Mobile Phone SMS (CAMPS) Trial: the Protocol for a Randomized Controlled Trial of Mobile phone text messaging versus usual care for improving adherence to HAART

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Reviewer's report:
I have only one issue that might be clarified. Three measures of adherence will be obtained. Will the data from those three be merged in some way? If not, how will possible differences in results from the three measures be handled?

Response:
We have revised the description of the primary outcome as follows (see page 7):

“The primary objective of this trial is to investigate the effect of adding the SMS to usual care versus usual care alone in improving and maintaining adherence to HAART in HIV positive patients on HAART at 3 and 6 months. There are several methods used to evaluate or measure adherence to medications, each with advantages and disadvantages. Thus, there is no gold standard in measuring medication adherence. The common approach is to use multiple methods to compare or assess the robustness of the estimates of adherence. For this study, we will use three commonly used measures of adherence – namely Visual Analogue Scale (VAS), Pharmacy Refill Data (PRD), and Self Report (SR). We will use VAS as the primary method of measuring adherence. The VAS is highly correlated with more objective methods like using Microelectronic Monitoring System (MEMS) caps. VAS method has also been widely used in several RCTs...
evaluating different interventions including mobile text messaging to enhance adherence to HAART [refs]. PRD and SR will be used to fill any missing data on VAS. Subjects will be considered either ‘adherent’ if VAS > 95. Similarly patients will be considered adherent based on PRD > 95% or SR > 95%. We will also analyse VAS, PRD and SR as continuous outcomes.”

We have also added the following description in the analysis section (page 9):

“In literature, adherence data can be handled in a number of ways. The measures can be reported as the number of doses respected or can be combined into a composite score. Even though combined measures are more correlated to clinical response, they are not very practical. The data from the various adherence measures will not be merged. We will report the effects of the intervention on all the measures of adherence used, and compare them for discrepancies. “

Additional changes:
The CDC and WHO classifications of patients are permanent and patients are not reclassified even if their clinical or laboratory parameters changes. This information will only be used for baseline comparisons. All references to these classifications have been removed from the abstract, main text, tables and figures.

All additions have been highlighted in yellow.