Author's response to reviews

Title: Assessing the Implementation Effectiveness and Safety of 1% Tenofovir Gel Provision through Family Planning Services in KwaZulu-Natal, South Africa: Study Protocol for an Open-Label Randomized Controlled Trial

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The formatting changes suggested have been addressed as follows:

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format “__________: study protocol for a randomized controlled trial.”

   The manuscript title now reads – ‘Assessing the Implementation Effectiveness and Safety of 1% Tenofovir Gel Provision through Family Planning Services in KwaZulu-Natal, South Africa: Study Protocol for an Open-Label Randomized Controlled Trial’

2. Please include the date your study was registered with the trial registration number at the end of the Abstract.

   The trial registration section now reads – ‘This trial was registered with the South Africa Department of Health (reference: DOH-27-0812-4129) and ClinicalTrials.gov (reference: NCT01691768) on the 05 July 2012.’

3. Please edit your ethical approval statement in the Methods section to state that ethical approval has been obtained, and include the full name of the approving committee, along with the reference number given. If full ethical approval has not been obtained, please let the editorial office know by replying to this email.
The Regulatory and Ethical Review section now reads – ‘This study is being conducted under the regulatory oversight of the South African MCC (reference number: 20110145) and the ethical oversight of UKZN’s BREC (reference number: BFC 237/010) and in accordance with International Conference on Harmonization guidance and GCP standards. The study was initiated after receipt of approval by the MCC (approval date: 21 May 2012) and UKZN’s BREC (approval date: 13 September 2012). The study is being conducted in accordance with all conditions of approval by the ethics and regulatory committees.’

4. Please replace ‘NK’ with ‘NN’ in the Authors’ Contributions section.
Done