Author’s response to reviews

Title: The Active for Life Year 5 (AFLY5) school-based cluster randomised controlled trial protocol Detailed Statistical Analysis Plan

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Author’s response to reviews:

Dear Editor,
Thank you for the opportunity to revise and resubmit this trial update.
The reviewer made just one comment:

“My only proposed amendment is to include the time when the plan was approved by the Trial Steering Committee. As the plan is dated 31st of January 2013, the data were released in February 2013 and we are now in April 2013, it isn’t clear whether the plan and any subsequent modifications were approved by the TSC and when. This could be clarified.”

RESPONSE

The final version of the analysis plan was approved by the TSC on 31st January 2013 and no analysts had any access to the data prior to that date.
This is not explicitly stated in the background to the document.

There was a delay between the formal submission of the document to the journal after TSC approval because of discussions with the editor about the best way to deal with this lengthy addition.

Yours Faithfully,
Debbie A Lawlor