Author’s response to reviews

Title: Protocol update and statistical analysis plan for CADENCE-BZ: a randomized clinical trial to assess the efficacy of sodium benzoate as an adjunctive treatment in early psychosis

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Author’s response to reviews:
21st January 2019

Professor Shaun Treweek
Editor in Chief,
Trials

Dear Professor Treweek,

We are grateful to you for arranging the review of our manuscript and grateful to the reviewer for the positive comments.

As requested, we have added in the section under the subheading 'Ethical and other approvals, and consent' so as to explain to the readers the steps we undertook to ensure the amendments were made with full disclosure and approval.

This section now reads

This amendment to the statistical analysis was approved by the Metro South Human Research Ethics Committee and by the independent Data Safety Monitoring Board established for the conduct of the trial. The trial was funded by the National Health and Medical Research Council (NHMRC) John Cade Fellowship APP1056929 who did not require us to submit a protocol. The NHMRC are updated of the study progress in annual progress reports of the studies. Consent was not applicable for this amendment.

Please advise if there are any further changes needed to this amendment

Yours Sincerely

James Scott
MBBS; FRANZCP; PhD.