Reviewer’s report

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

Version: 0 Date: 15 Jan 2019

Reviewer: Shaun Treweek

Reviewer’s report:

Editorial comments.

As this protocol amendment is part of an externally funded project and received ethical approval and data monitoring committee approval (confirmed by Prof Scott via email), this manuscript just needs to be checked for reporting issues.

The text is clear and describes the changes well. The only change I'd like to see is to provide the information that we got by email re. approvals in the protocol amendment text. The easiest place to add it would be under your existing 'Ethical approval and consent' (perhaps now called 'Ethical and other approvals, and consent'. The text to be added would be something like:

"This amendment to the statistical analysis was approved by our ethics review board [name] and by the trial data safety monitoring board. The funder (The John Cade Fellowship) did not require us to submit a protocol but is updated of any changes in annual progress reports of the studies. Consent was not applicable for this amendment."

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Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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