Reviewer's report

Title: Baseline characteristics and Statistical Analysis Plan for the 'Prevention Of Decline in Cognition After Stroke Trial' (PODCAST) trial

Version: 2
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Reviewer: Steff Lewis

Reviewer's report:

Baseline characteristics and Statistical Analysis Plan for the 'Prevention Of Decline in Cognition After Stroke Trial' (PODCAST) trial

This paper describes the baseline characteristics (combined across treatment groups) from the feasibility phase of the PODCAST trial; describes the various protocol amendments through the trial; discusses that the main phase of the trial is not feasible; and gives some blank dummy tables that will be used in the final analysis.

The protocol has previously been published, and the final analysis paper will be forthcoming. I am in favour of publishing Statistical Analysis Plans ahead of the final report.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. The title should reflect what this paper is: it should mention that this is an assessment of the feasibility of the main phase – currently this first appears in the conclusions of the abstract.

2. Once the title is fixed, the rest of the paper should flow from it. For instance, if this is a paper about assessing feasibility, then the planned Methods and appropriate Results for assessing feasibility should be included. If the title contains the statistical analysis plan (SAP), then the Methods and Results should describe this. A full SAP should be included in the body of the paper, and not just as an appendix without further comment (the current appendix is not an adequate SAP – it is missing much of the detail that is normally in a SAP). If the title is about baseline data, then the Conclusion should say something about whether the data were as expected.

3. The interim analysis results have already been made public, apparently according to the Statistical Analysis Plan. This Statistical Analysis Plan should be presented here, so that the reader can be reassured that the SAP was finalised before the results were made public (and also because a Statistical Analysis Plan was promised in the title).

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

4. Table 3. Spell out IS in the footnote.

Discretionary Revisions (which are recommendations for improvement but which
the author can choose to ignore)

5. The trial has only a small number of participants, yet the results are going to be adjusted for several covariates. It might be worth adjusting instead for a propensity score, as suggested in: E. J. Williamson, A. Forbes, and I. R. White. Variance reduction in randomised trials by inverse probability weighting using the propensity score. Statistics in Medicine 33:721-737, 2014.

6. The paper says that the trial ran in primary and secondary care, yet the protocol only mentions secondary care (as far as I can see). Was there a protocol amendment relating to this?

7. It is slightly misleading to say in the abstract that 83 of 100 planned patients were recruited. It was really 83 of 600, and the target was reduced down when recruitment was not as expected.

8. Could the information copied from the Protocol (in the Methods section) be shortened, to leave more space for new information?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.