Reviewer’s report

Title: Protocol for the STAR (Sheffield Treatments for ADHD) project: a pilot study assessing the feasibility of the Trials within Cohorts (TwiCs) design to test the effectiveness of interventions for children with ADHD

Version: 0 Date: 17 Oct 2017

Reviewer: Susanna Dodd

Reviewer's report:

This is a well-written comprehensive protocol. However, the structure of the protocol could be enhanced by introducing subheadings within each section.

The last section of the Background should be re-written to provide the Aims and Objectives, which should link directly to the Outcomes.

The Methods section should include the following headings: Inclusion/exclusion criteria, Randomisation, Outcomes, Statistical analysis, Sample size.

In the Outcomes section (which currently is placed under the "Results" section), please could you differentiate between "feasibility outcomes" and "patient-centred outcomes". You have listed primary and secondary outcomes (in the Results section) - these are the patient-centred (or efficacy) outcomes. You have described feasibility criteria in Table 2 - these relate to the feasibility outcomes. It would be useful to combine these together in a new "Outcomes" section in the Methods. This section should explain how you plan to measure the feasibility outcomes (ie it should include the information and footnotes given in Table 2.)

Regarding randomisation, please can you explain how allocation concealment is achieved, and how the randomising clinician will be informed of the next allocation? (For example, does the clinician phone the statistician who has the list locked in their desk drawer to find out the next allocation)?

Stratification information (found on p8 line10 and p10 line 40) should not include the block size - please remove this information.

Statistical Analysis (currently found in the Results section):
p13 line 3: "Baseline data will be adjusted for potential co-variates such as..." I think you mean that the outcome will potentially be adjusted for these additional covariates in the ANCOVA model? Please reword this sentence to clarify your meaning.

p13 line 57: Please emphasize that this study is not powered to detect significant differences; hence analysis will focus on confidence interval estimation, rather than hypothesis testing, and that any statistical testing will be considered as exploratory.

p13 line 27: As the study is not powered to detect significant differences in the characteristics of patients who do/not accept treatment, I would suggest that you instead assess these differences clinically (rather than statistically).

p14 line 22: Similarly, I would suggest that you add "clinically significant" before "differences" in this sentence.

p13 line 57: Can you give a bit more information about how you plan to carry out the CACE analysis, as I don't think this is possible in SPSS?

I have a few additional minor comments:


p4 line 37: add a semi-colon after reference [28]

p5 line 29: add a semi-colon (instead of a comma) after "pocket"

p8 line 27: add an "s" to ask (ie asks)

p9 line 11: remove comma after 55

p13 line 5: capitalise "l" in "last" (ie Last)

p 15 line 13: remove bracket and space after "consultation" ie ") "

Table 1: add horizontal line between rows showing T scores of 70+/66-70
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