Reviewer’s report

**Title:** Coping with Persistent Pain, Effectiveness Research into Self-Management (COPERS) - statistical analysis plan for a randomised controlled trial

**Version:** 1  
**Date:** 3 January 2014

**Reviewer:** Julius Sim

**Reviewer’s report:**

This is an interesting and clearly written account of the proposed analyses in this trial. I have no compulsory revisions to suggest, as the analyses will already have been specified in the definitive published protocol (and in any case strike me as appropriate).

Given that the analysis plan is to be published in a journal with a broad clinical trials readership, I think a comment or two in places on the rationale for particular analytical choices would be of interest and instructive to the general statistical/trialist reader. In this way, the paper would have an appeal to a readership beyond those solely interested in the specific analyses in this study. Similarly, some more references relating to some of the key methods and statistical issues could be cited.

Discretionary revisions:

Under 'General analysis principles':

You might wish also to report the test statistic and df, when one or both of these are appropriate.

It is stated that continuous covariates will be assumed to have a linear relationship with the outcome. This is rather ambiguous. Do you mean that this is an assumption of the analysis (and will therefore be tested in the normal way), or that this assumption will simply be made a priori, with no verification against the data?

Under 'Analysis of primary outcome':

"Participants who did not fill out any portion of the CPG disability score at either 6 or 12 months will be excluded from the analysis". Ambiguous as to whether this means '6 months or 12 months or both' or 'both 6 and 12 months'. Suggest rewording.

"In the intervention group, multilevel imputation will be performed, with 'course' included in the imputation model as a random effect". Presumably this is why imputation is to be undertaken in each group separately (stated about 8 lines earlier), so perhaps place these two statements together.

Under 'Method of accounting for missing data':
In the first bullet point, perhaps be a little more explicit as to which covariates are referred to as 'additional'.

"The analysis model will be the same as that for the primary analysis, except missing baseline covariates will be replaced using mean imputation". A similar statement later is referenced to White and Thompson - it would be appropriate to do so here also. In addition, whilst this is a very clear statement of what is intended, it might be helpful to the general reader (i.e. one who is interested in the underlying statistical issues) to briefly state the rationale for this choice of imputation (e.g. instead of hot-deck or some other method).

The analysis described under 'Redefinition of primary endpoint' to account for misinterpretation of the scales by participants sounds an excellent idea, and will be of interest to readers who might use the CPG questionnaire (or similar scales).

Under 'EQ-5D at 6 and 12 months':

"EQ-5D scores with missing components will be regarded as completely missing". I would clarify this statement. At first reading I thought it meant that the missing score would cause the case to be excluded from analysis, but then it became clear that it meant (I think) that no attempt would be made to infer the missing component scores from those that component scores that were present, but that imputation of the total score would take place.

Under 'Adherence-adjusted analysis':

The general reader might value one or more references to CACE.

Table 1:

It is not clear what elements are part of the core COPERS course. Is it just those numbered 1-10, with art, hand massage and volunteering being associated activities, or are all of these core elements in the course? Perhaps expand the figure legend to make this clear.

General:

Hyphenate compound adjectives (group-based, three-day, pain-related, etc).

Initial capitalization of words in journal titles needs some attention, and also formatting of references in journal style.

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