Reviewer's report

Title: Reporting of participant flow diagrams in published reports of randomized trials

Version: 1 Date: 6 October 2011

Reviewer: Hywel Williams

Reviewer's report:

Major compulsory revisions
None

Minor essential revisions
1. Given that one of the 'terrible' findings of this report is that only 54% of the trials investigated stipulated the numbers of study participants included in the main analysis, I would like to see a little more unpacking of that vital statistic. I am aware that you have examined 25% subset to see how well such missing information could be gleaned from the paper and in what time, but the sort of information on this rather important parameter is usually very easy to get from looking at tables 2 or 3 or graphs from the published report. Could you comment specifically on the time taken to find this information and the completeness of this information from the text of the main written report?

2. You have shown that there are clear deficiencies in the completeness of following the reporting and CONSORT participant flow charts, but I would like to see you concentrate more on the solutions in the discussion. I work as clinical trials editor to a specialist journal, and although I have made great strides with the journal to ensure that authors complete the CONSORT check list and to get authors to indicate where in the revised manuscript they have included the various items, plus a flow chart, expecting me to check that every single item on the CONSORT participant flow chart has been filled in, is too much. Most specialist journals will not have the resource to do that, and most volunteer referees like me will not want to spend an extra 10 minutes on a Sunday morning looking for such detail. Surely, this is a problem that could be solved overnight by adopting comprehensive software that enables people to do their flowchart with forced fields (like the website you cite at Washington). I have had a play with that website from Washington, and although it is a great start, it is not comprehensive as it only applies to two-arm trials, it does not allow cluster trials as far as I can see, and it does not do any logical range checks or automatic checks whether the numbers add up, so it is possible to put wrong numbers into it. A more refined version of this instrument would be a great idea, and if all journals (general and specialist) simply referred their trial submissions to this website, then the problem might be solved overnight. I do appreciate that the problem, as usual, belongs to us 'all', ie. authors, referees, editors, funders, etc., but this is one of those situations where a piece of software that is universally adopted (and perhaps
developed by the CONSORT group?) could come up with a very powerful solution that would not take 17 years to change things. So I would like to see more focus on this aspect of the discussion, especially the software solution, perhaps at the end of the abstract.

Discretionary revisions

Overall I found this manuscript very clearly written and helpful. The rationale for focusing on just participant flow diagrams is justified as it is arguably the most important feature of CONSORT reporting, especially as one diagram often allows a much quicker understanding of exactly what went on in a trial compared with lots of text. One could of course do an analysis like this for each of the items of CONSORT, in salami style, but a stand alone publication on participant flow diagrams is justified in my view.

The two ‘terrible’ statistics are the 40% reporting of the numbers who actually receive the allocated intervention and the 54% that reported the number included in the main analysis. I think these could be brought out more in the discussion and abstract but this is very much up to you.

I am glad that you have done your own decent study inclusion flow chart in Figure 2! You don’t want to be tripped up by your thesis after all.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have none.