Reviewer's report

Title: A Systematic Review of Techniques and Inteventions for Improving Adherence to Inclusion and Exclusion Criteria During Enrolment into Randomised Controlled Trials

Version: 1 Date: 16 December 2009

Reviewer: An-Wen Chan

Reviewer's report:

The authors present an excellent systematic review on an important topic. My comments are minor and mostly for clarification.

Minor Essential Revisions
1. Page 4, para 2 -- Capitalize MEDLINE
2. Page 12, para 1 – ‘associateD’

Discretionary Revisions
1. Is the term ‘eligibility criteria’ preferred to ‘inclusion and exclusion criteria’, as an inclusion criterion can simply be the reverse of an exclusion criterion (eg. Include >17 yrs old vs exclude <18 yrs old)?
2. Should the paper discuss that a contributing factor for lack of adherence to eligibility criteria could be poor definitions of criteria in the trial protocol?
3. Page 3, paragraph 1 – Brief examples or elaboration on what harms may occur due to enrolment errors would be useful.
5. Page 8, para 3 – “…has been shown to result in most harm”
   Is this assertion warranted based on reference #2? Did the study compare harms resulting from various types of protocol violations and find a significant difference? It would be helpful to elaborate on how harms may arise due to enrolment errors.
6. Page 11, para 4 – There are many uses of the term ‘ITT’. Should ‘ITT’ be defined in the text?

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 declare that I have no competing interests