Reviewer's report

Title: Pragmatic trials in primary care Methodological challenges and solutions demonstrated by the DIAMOND-study

Version: 1 Date: 7 March 2007

Reviewer: Shaun Treweek

Reviewer's report:

General

The authors have made a serious effort to address the concerns I raised in my first review of this paper but I still don't think that the paper is quite ready for publication. My main concern is that the paper aims to provide general guidelines for designing and running a pragmatic trial in primary care, using DIAMOND as an example, but what it really does is explain the rationale behind the decisions made in the DIAMOND trial. The latter is useful and worth reading about because it is rare to see such a publication but by trying to package this information as something akin to guidelines the authors overstretch themselves. The ‘publication as guidelines’ approach requires a much more systematic review of the literature as an introduction to each section (eg. ‘Choosing the right intervention’), which is then illuminated by a careful description of the rationale behind the decisions and judgements made in the DIAMOND trial. The current paper doesn’t do this; the introductions are generally lightly referenced, there are few systematic reviews in the reference list and the DIAMOND descriptions are not closely linked or interpreted in light of the introductions.

In my first review I wrote ‘However, the design and conduct of the DIAMOND trial does have a bearing on how good a case study the trial is as a model pragmatic trial that can be used to provide methodological solutions to other trialists and researchers, which is the aim of the article’. What I meant by this sentence was that how the DIAMOND trial was designed and conducted has a direct influence on how good an example of a model pragmatic trial DIAMOND is (ie. if these choices were poor, then it is a poor example). What I was hoping to see in the new draft was a clearer description of the rationale behind the design and conduct decisions taken in the DIAMOND trial and how these choices made the trial more relevant for patients, clinicians and policymakers. I expected this to lead to paper that was more limited in scope than the current paper. Instead, the new draft has kept its ambitious scope and got longer without really helping the paper to meet its ambitions. This could be a useful paper but not in its current form.

In this regard I have a number of specific comments, which are listed below under the headings used by Biomed Central.

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

Discussion (general for all sections)
1. I’m going to repeat what I said in my previous review - ‘But this paper also aims to give guidance so that other trialists can learn from these experiences and improve the quality of their own pragmatic trials. Here I think the authors need to think a bit more about how they present their experiences from DIAMOND so that they can be as useful as possible for other trialists.’

2. With this in mind I think the authors should reduce the scope of their article so that they give a brief introduction to the sorts of issues faced by trialists when choosing their intervention and then ‘..present their experiences from DIAMOND so that they can be as useful as possible for other trialists.’

3. And then at the risk of seeming boring, I’m going to repeat another comment from my first review - ‘What think is needed in addition is some comment on exactly how and to what extent this final decision increased (or decreased) the usefulness and relevance of the trial’s results to patients, clinicians and policymakers. Why did this choice, rather than some other choice, make the trial more relevant to people working with, or receiving treatment in, Dutch general practice? Maybe a new subheading could be used - ‘Why our choice made DIAMOND more relevant to patients, clinicians and policymakers’. A bit long-winded and not very exciting but you get the idea.’ (A better subheading would be ‘Rational behind the choices made in the
DIAMOND trial'). I still think that this should come at the end of each section rather than the brief single section at the end of the new draft. I take the authors' point that the paper is getting long - I suggest that the authors provide individual sections on why these choice made DIAMOND more relevant and useful but that they make their introductions shorter and their writing in general a bit tighter. Some sections are extremely wordy.

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

Background
Page 4: I'd add a subheading 'The DIAMOND trial' above the paragraph outlining the trial.

Protocol deviations
Page 19: If the question asked of patients is along the lines of ‘Has symptom relief been adequate since the start of treatment?’ then I’d replace the word ‘complaints’ with ‘symptom relief’ since this is closer to the authors’ earlier choice of phrase on Page 12.

Summary
Page 21: I guess that when the authors mention priorities, they are suggesting that trialists should consider where on the pragmatic - explanatory spectrum they want their trial to be. This is a good thing to emphasise.

Box 2 and Box 3
Change ‘in- and exclusion..’ to Inclusion and exclusion criteria.

Discretionary Revisions (which the author can choose to ignore)

Discussion - Choosing the right intervention
Page 5: I'm still not convinced about the authors’ arguments re. blinding affecting generalisability although I'm willing to simply accept that we have a difference of opinion. My feeling is that if it is possible to blind then a trialist should do this because the bias introduced by an open trial (or perceived as being introduced) runs the risk of undermining the trial's results. This is likely to affect generalisability since doubt about the trial results will make it hard to use the trial as a basis for changing professional behaviour. If an intervention is shown to work in a blinded trial then it is the job of those charged with rolling the intervention out into routine care to attempt to address any prejudice against the intervention among stakeholders. Solid trial data showing that the intervention is more effective than stakeholders’ current favoured intervention should help rather than hinder I would have thought.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

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