Reviewer's report

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

Version: 1 Date: 5 March 2007

Reviewer: Martin Dawes

Reviewer's report:

General
This article lucidly debates issues about pragmatic trials. I do still have an issue that the authors have not explicitly quoted information on the quantitative aspects of blinding, that the absence of blinding may overemphasize results by as much as 15% juni et al. Secondly a pragmatic trial might explore GP preferences for treatment which may be a factor that could be used in a sensitivity analysis for reducing the impact of lack of blinding.

I would have expected to hear something about equipoise in the discussion on recruitment. I would also have expected a pragmatic study to identify the actual pattern of severity in the target population in primary care non research practices and then compare this distribution with the distribution of severity in the recruited population, and not compare it to other research populations who are unlikely to represent the ‘real’ population.

Outcome measures were defined by experts and we should be moving to patients helping determine outcome measures relevant to themselves.

I have included all my remarks in the general section as I think that the article should now be published as is. My response is not so much on the scientific quality of the article but more as a reader responding to the authors.

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

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

Discretionary Revisions (which the author can choose to ignore)

see above in general section:

What next?: Accept after discretionary revisions

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