Reviewer’s report

Title: An investigation of minimisation criteria

Version: 1 Date: 21 December 2005

Reviewer: Marion Campbell

Reviewer’s report:

General

This paper describes the results of simulations to describe the influence of varying certain minimisation factors (eg number of factors, randomisation “bias” to use) on balance in a randomised controlled trial. The authors present the results of a small selection of simulations to illustrate the consequences of varying minimisation factors. With the use of minimisation increasing in the literature, this is a useful addition to the literature in the field

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

The authors show that varying the choice of minimisation parameters impacts on the resulting balance across groups in the randomised trials. Whilst this is true, the choice of factors (and their cutpoints) should be informed primarily by the clinical importance of the factors (and their potential impact on outcome) rather than by a potentially artificial simulation exercise. A section should be added to the discussion section highlighting the potential tensions between the two approaches. However, the authors are right to indicate that their simulation package will help with the choice of cut-point if there is no clinical reasoning to inform this judgement.

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

1. The paper would benefit from the inclusion of a worked example of minimisation to help the non-specialist reader understand the processes involved.

2. The authors should give their rationale for the choice of using 5000 simulations – what informed this decision?

3. The authors chose “typical” examples to simulate – what evidence do the authors have that these really are typical scenarios?

4. The authors comment that “clinicians do not find it easy to keep running totals and perform biased randomisations”. Given the importance that is put in the literature on concealment of allocation, this is probably an added benefit of minimisation ie that the randomisation must be handled centrally. The authors should stress this more explicitly.

5. The authors indicate that more information should be included in the protocol about the minimisation process. However, some authors have argued the opposite – that minimal information on the randomisation process should be available until recruitment to the trial has closed (this is to prevent any information being available which could aid potential subversion of the randomisation scheme). I agree with the authors, however, that this information should be provided more fully in the trial report.
6. The scale on the y-axes on the figures differ – this makes direct comparison across them difficult. They should be standardised.

Discretionary Revisions (which the author can choose to ignore)

None

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

Declaration of competing interests:

I declare that I have no competing interests.