Reviewer's report

Title: Balance algorithm for cluster randomized trials

Version: 1 Date: 2 July 2008

Reviewer: Gillian Raab

Reviewer's report:

Major compulsory points

The reasons why a randomisation element are considered essential for RCTs are not discussed. In particular the use of randomisation allows randomisation inference rather than model based inference to be used for analysis, and this is often thought to be more robust to model misspecification. See reference below for a discussion in the context of CRCTs. If it is intended to use the randomisation distribution for inference then a criterion as to how many units are to be selected will be the that the total number in the randomisation distribution must be sufficient to provide interval estimates that are sufficiently accurate. This means adequate precision at (say) the 2.5% and 97.5% percentiles. With the blocking approach discussed here, one presumes that the group for inference might be all possible combinations of selections from each block whcih would be a pretty large number.

Covariates in CRCTs are often categorical, e.g. type of clinic. How would the program handle this? Would you divide into subgroups? Or define some sort of distance measure between groups, In particular how should one proceed with several of these?

Specific points

Page 2 wij is not defined although one assumes it is a weighted Z score. This should be explained and the choice of weights discussed, if only to say that equal weighting will often be appropriate.

By looking at the R programs, this standardisation seems to have been carried out within each block, rather than over all the prectices (which might be considered more appropriate). This should all be discussed and justified.

The balance criteriaon defined by equation 1 in the paper differs from that defined by equation 9 or Raab and Butcher.

The latter uses (1,-1) in place of the (1,0) for the xs used in this paper.

If the standardisation to z sores is carried out within blocks, then I think that the two equations are equivalent,
Results
I would much prefer that a real rather than hypothetical example were used.

Discussion
How is concealment a problem in a CRCT. Allocation is usually done as a group, so concealment is not the same as in individual patient trials. This should be explained.

Optional points
On the numbers of allocations to use for selection, why not take the same proportion of each block?
The term 'seed' used for previous block results is not a good use of this term. Preliminary result might be better.

Reference
DOI: 10.1191/1740774505cn075oa
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Randomization inference for balanced cluster-randomized trials
Gillian M Raab and Isabella Butcher

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

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests