Reviewer's report

Title: Recruiting for a multicentre randomised controlled trial in Bells Palsy: A case study

Version: 1 Date: 19 January 2007

Reviewer: Peter Bower

Reviewer's report:

General

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

The issue of recruitment is of interest to the wider primary care community, given the significant problems in this regard. Therefore papers analyzing this issue are to be encouraged.

This paper is a description of the process of recruitment to a trial of a rare condition. The authors hope that the description of their experience will be of use to other researchers.

The authors have clearly done an incredible job recruiting patients, and should be congratulated on their efforts and their success.

As the study is largely descriptive, I had few major comments on the overall presentation, which seems largely straightforward and unproblematic.

Notwithstanding their success in recruitment, the paper has to be judged on whether it advances our understanding of recruitment issues, and whether it will have an impact on this area. I think this is problematic with papers on this topic generally (and is certainly not specific to this one). The suggestions made by the authors were all appropriate and sensible, but I felt that there was an insufficiently critical approach to some of these issues which would benefit from some additional consideration. As an example, in the conclusions in the abstract, it seems to be implied that if only people used planning, developed good relationships and minimized workload then recruitment would be successful. However, I can think of many trials that did exactly this and faced the usual problems. Their description of the minimal involvement of doctors on page 8 seems like a fairly routine description of what is asked of GPs in many trials. Can the authors identify why their study was different? Clearly they are doing something right, but it is not clear to me what the key ingredient is.

a) I was interested in the description of the recruitment process as ‘evidence based’. The controlled trial literature on recruitment strategies is tiny (and a recent review might usefully be referenced by the authors). What exactly did the authors mean by this term? How many of the ‘key issues’ discussed on page 12 could be described as truly evidence based, as opposed to simply being sensible suggestions which may or may not be important in certain contexts?

b) The authors describe the key success factors for the study on page 12, but I think a more critical approach to this issues would be useful. They state that the study addressed a clinically important research question, but how is that to be judged? Do they have an independent indication of this, beyond the successful recruitment? How many primary care studies would claim to be answering a clinically important research question, and still face the usual recruitment problems? And what about the downsides of this issue – what happens to those trials that wish to examine issues that are not viewed as ‘clinically important’ (presumably by recruiting clinicians), but still address important questions?

c) The same issue applies to the factor concerning the workload of referring doctors. Although it makes intuitive sense that workload is an issue for doctors, how many trials adopt the same low workload approach and still fail to recruit? Is a reduction in workload enough? Again, my impression is that almost all trials adopt this approach, and while I do not doubt that high workload trials will struggle to recruit, I do not believe that low workload is necessarily a determinant of successful recruitment either.

d) Similarly, they highlight the importance of a trial coordinator, but one trial of the importance of a trial.
coordinator visiting recruitment centres suggests that it is not helpful. So is their approach really evidence-based? The same is true of payment to recruiting clinicians (again, there is another recent review which should be referenced, which indicates that there is essentially no evidence base).

e) I accept that a willingness to recruit patients seven days a week is potentially very useful as a way of improving recruitment, but it would be helpful if the authors could indicate how frequent that was required and the resultant burden on research staff. That information might be practically useful in the planning of future trials with seek to be so accommodating.

f) Similarly, the authors highlight the importance of forming good relationships with patients, but it is not clear that they were any better at this than any other trial, so I wonder about the importance of that suggestion. Did they make special efforts in this regard? Are they suggesting that this was the reason that patients were less likely to be lost to attrition? Are there any downsides of such ‘good relationships’ in terms of bias in the assessment of outcome?

I do not wish to appear overly negative, as the success of their trial clearly shows that this group have something important to say. However, I felt that the authors might be encouraged to be a little more critical in their presentation, and try and present a more balanced discussion of the importance of the various issues and their practical implications for trial delivery.

It might also be useful for them to crudely quantify the amount of effort they had to put into recruitment via the various activities that they undertook. After all, such activities are not without their own opportunity costs. That will inevitably lead onto concerns about which activity was most important, and the authors might usefully consider this issue as well.

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

I would prefer that the paper concentrated more on the trial recruitment strategies, and less on the trial. Having said that, I did not understand the relationship between the various research visits made to the patients’ homes and the telephone follow ups. I wonder if this detail might be removed.

I did not understand the comment on page 12 that ‘we retained a higher proportion of patients in the study than we had anticipated’ which references the table, since the table simply includes a list of reasons for loss to follow up.

I wasn’t sure of the utility of table 1, since this seems very specific to the particular trial, whereas this paper is trying to draw lessons about recruitment in general. The same could be said for Box 1, which adds little. I also thought that tables 2 and 3 could be summarized in the text. Would it also be helpful to present the data in table 4 as a proportion of eligible cases recruited, as opposed to the actual difference in numbers?

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Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential 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.