Author's response to reviews

Title: Recruitment and retention in a multicentre randomised controlled trial in Bells palsy: A case study

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Author's response to reviews: see over
Dear Colleague,

**Recruitment and retention in a multicentre randomised controlled trial in Bell’s palsy: A case study**

Thank you for reviewing our paper and for the many useful comments you and the reviewers have provided. We believe we have incorporated all their suggestions and believe that the article provides useful information for others who may seek to research uncommon conditions.

We have added some new data and as you suggested greatly reduced the specific information about the Bell’s palsy trial itself. We did think it was important to provide some detail about the trial, however, so that the context may be understood.

With regard to specific comments:

**Tom A Trikalinos:**

We believe that the revised paper with its additional material does represent useful information which will help other researchers plan studies of this kind.

**Peter Bower:**

_There was an insufficiently critical approach to some of these issues which would benefit from some additional consideration_

We have greatly expanded the discussion section of the paper and now critically discuss in the light of the (relatively sparse) literature on recruitment the possible impact of the approaches we felt contributed to the success of the project.

_The controlled trial literature on recruitment strategies is tiny (and a recent review might usefully be referenced by the authors)._ We now refer to the literature throughout the discussion and quote the recent Cochrane review by Rendell et al.

_The Impact of the importance of research on willingness to recruit_

The evidence for importance of research is somewhat contradictory and we now discuss this. We also now make it plain that GPs approached in the pilot phase of the work regarded the subject as important. This was one of the reasons we embarked on the research. Clearly it is likely to be a problem for researchers to get clinicians to recruit to trials on areas that are not of importance to them and other than suggesting involving the other methods we describe in our paper we can only acknowledge this.
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?

We have expanded this section clarifying that the trial in this case probably constituted a reduction of workload compared with normal care rather than a minimal increase in workload as is the case for many trials.

*Experienced Trial co-ordinator*

While we believe a good trial co-ordinator to be an essential part of any project, this was not meant in isolation what we said was

“an experienced trial co-ordinator and dedicated researchers willing to recruit participants seven days per week”

We have expanded the section on out of hours recruitment and follow-up detailing the major role this played in the overall recruitment. At the time of recruitment it was made clear to research staff that this project would require some evening and weekend work which they accepted. Researchers were able to take ‘time in lieu’ for this type of work.

*Payment to recruiting clinicians*

We have added a discussion of the evidence for and against this.

*The importance of forming good relationships with patients*

We agree with the reviewer that we have no evidence we did this any better than any other trialists and have therefore removed this section.

*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*

We have provided estimates for the various activities where appropriate.

*Which activity was most important...*

It is always difficult to be sure which of many activities was most productive. However, we believe on balance that the willingness to recruit out-of-hours probably had the greatest impact and we now say this.

*Carien Beurskens:*

**Major Revisions:** 470 has been substituted for 480 (thank you for spotting this). The rational for House Brackmann has been added (it was the recognised US standard at the time of the study design.) The timing of the end point has been clarified.

**Minor essential revisions.** Thank you. All of these typos have been attended to. All abbreviations have been expanded.
I would prefer that the paper concentrated more on the trial recruitment strategies, and less on the trial.

We have greatly reduced information about the specific trial but have left enough to provide a context for the paper.

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.

This has been removed.

Concerning the end-point what was the time for this?

If the patient was considered to have resolved following the second visit the patient was visited a third time and considered to be resolved or not. Resolution or lack of it at nine months was the end point (now clearer in the text)

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.

This along with much of the detail of the trial has now been 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

Utility of Box 1 and tables 1-3 and content of table 4

We have removed Box 1 and tables 1-3 and believe the text which incorporates some of this data is now clearer. We have moved some of the material from tables 1-3 to the text. Table 4 (now table 1) has been altered to reflect the proportion of actual cases recruited as requested.

What if patients had a Bell’s palsy in their previous medical history, are these patients excluded? The literature reports namely a recurrence of 3 – 11 % of the patients with a Bell’s palsy

We did not specifically exclude any patients who had previously had Bell’s Palsy.

The incidence in Scotland (25-35 per 100 000) seems to be higher than in other parts of Europe and the USA (20 per 100 000)

We have included the most recent review on this subject (published after our trial had commenced) by De Diego-Sastre (2005). In most of the series published incidence oscillate between 11 and 40 cases per 100,000 inhabitants per year, although figures as low as 8 and as high as 240 cases per 100,000 inhabitants per year have also been reported. The Scottish incidence seems to be in the middle of the range.
We hope we have met the concerns of the reviewers. Please let us know if there is anything further you wish us to do.

Yours faithfully

Brian McKinstry