Author's response to reviews

Title: Feasibility and results of a randomised pilot-study of pre-discharge occupational therapy home visits

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Author's response to reviews: see over
Response to reviewer’s advice on MS#1891026159125357 “Feasibility and results of a randomised pilot study of pre-discharge occupational therapy home visits”.

Thank you for your email of 23 January 2007, and feedback on the paper. This feedback has provided us with invaluable expert advice which has guided our review of the paper. We have acted on each reviewer comment, and now forward a revised paper for your consideration.

This letter details our action for each reviewer recommendation.

Reviewer 1: Major Compulsory Revisions

1. “My main concern is the small sample size and the use of inferential statistics to analyze the data. Because the power is so low, I would recommend just looking at the descriptive statistics and commenting on what they show. If clinical significance is used to assess the impact of the intervention implied by the descriptive statistics, it would be important to state how it was defined.”

We recognize this issue as one of statistical contention and have taken on board the reviewer suggestion and clearly reported descriptive statistics. Further, we accept that the small sample dictates only the most conservative interpretation of these data and this is now more clearly stated in the revised manuscript (under Results, subheading Outcomes, Line 1).

We have, however, chosen to keep in the inferential statistical analyses for the following reasons: (a) reporting of confidence intervals on the estimate of effect allows readers to judge for themselves the impact of sample size in the absence of a power calculation. We do agree that for the majority of outcomes, the confidence intervals demonstrate that the study was insufficiently powered, however NEADL results provided confidence intervals which, although wide, do not span 0 and are above the minimum worthwhile treatment effect; and (b) the results of inferential tests are generally more useful to readers (for example, inferential statistical results can be included in meta-analyses).

2. “Another value of the study which the authors might note is how the observed effect sizes could be used to calculate required sample sizes for future studies. I am always grateful to get tips on ways to improve large studies by the results of pilot-type research.”

This information has been inserted in the Discussion (paragraph 5, last line) with relevant citations.

Reviewer 2: Major Compulsory Revisions

3. “In the last paragraph of the Introduction the authors should explicitly state that the primary aim of the study is to investigate the feasibility, whereas the secondary aim is to explore possible treatment effects.”

This is now clearly stated within Introduction (last paragraph).

4. “With regard to the efficacy analyses, I also advice the authors to stress (both in the Introduction and in the Discussion section) the importance of collecting pilot data so that - in the preparation of a future full-scale trial
- an appropriate choice for a primary outcome parameter can be made, including the need for data to perform a sound power-analysis.”

This is now more clearly discussed within Introduction (last paragraph) and Discussion (paragraph 5).

5. “In the Discussion section, the authors correctly raise point by point what they have learned from this pilot, and how to use this information in a future trail. However, in this section some methodological aspects deserve more attention:
   a. First, the authors should discuss the methodological /ethical problem how to avoid Hawthorne effects in patients when informing them completely about the purpose of the study. Hence, unblinded patients who assess outcomes after being informed about the different treatment options during recruitment might bias the results of a study. The likelihood of bias increases when patients have a preference for one of the treatment options (see also BMJ 2003;327:284-285).
   b. Second, it should be stressed that in the future trial the care (and control) treatment has to be delivered by a broad range of occupational therapists within a multi-centre design. Not only, to improve the generalizability of the findings, but also to ascertain that the outcomes of the treatment is the result of the specific characteristics of the care program, and not the result of some individual qualities of one or two care givers involved.
   c. Third, point on the importance of using checklists to assure a standardized delivery of the care program.

These three parts have been inserted in the discussion. The dangers and difficulties of the Hawthorne effect and use of self-rated (unblinded) measures, the necessity to increase staffing numbers to improve generalisability, and the importance of using standardized checklists in the delivery of the treatments have each been summarized with relevant citations.

6. “The statistical paragraph is not completely clear. The repeated data structure in combination with the use of GLM suggest a repeated measurement analysis. Table 2, however, shows a between-group analyses on each time point. This suggests that the authors used ordinary linear regression adjusting for pre-treatment scores. Am I correct? Please, explain.”

Data was analysed using ordinary least squares regression adjusting for baseline scores in analyses to allow comparison of outcome at different time-points. This has now been more clearly reported in the statistical paragraph of Methods (subheading Analysis).

Reviewer 2: Minor Essential Revisions

7. “Please, delete the p-values in Table 1. Assuming that the randomization was unbiased, baseline differences between treatment groups are per definition based on chances and as such p-values are redundant in this context.”

p-values have now been deleted from Table 1.

Reviewer 2: Discretionary revisions

8. “Background: Please delete in the in fourth paragraph the term (n=60), since this number does not say anything about the question whether the concerning study was (in)sufficiently powered.”

This term has now been deleted.

9. “Methods-outcome assessments Please give additional information about the blinded assessor. What was his or her professional background? Was the assessor one of the authors?”
Details of the blinded assessors have now been included in the revised paper (under Methods, subheading Random allocation), indicating that the assessors were occupational or physical therapists; NL (author) was responsible only for baseline assessments prior to group allocation.

10. “Discussion: In the first paragraph the authors state that the study turned out to be feasible in terms of data analysis. Please delete this last remark as statistical analyses, if appropriately performed, are always feasible. You don’t need a pilot study to explore this issue.”

This statement has now been deleted.

Yours sincerely,
Christine Lin