Author's response to reviews

Title: Specific treatment of problems of the spine (STOPS): design of a randomised controlled trial comparing specific physiotherapy versus advice for people with subacute low back disorders.

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Version: 2 Date: 25 April 2011

Author's response to reviews: see over
25th April 2011

Dear Editor

I am pleased to submit my revised manuscript for consideration of publication in BMC Musculoskeletal Disorders. The comment of the reviewer has been addressed below, and also within the manuscript as indicated by yellow highlighting of the modified text.

Reviewer comment:
“There could be a bias related to the effect of attention. The “advice” group receives only 2 sessions, whereas the “specific” group receives 10 sessions. Thus, greater attention per se in the specific group could lead to better outcomes. This is especially the case as questionnaires, and no objective measures, are used. My advice is to give both groups equal amount of attention”.

Author response:
During the design stage of our trial, strong consideration was given to the choice of a control intervention. We chose to conduct a pragmatic RCT that compared our new classification-based treatment to the existing treatment of advice in its usual clinical form. We have provided comment in the discussion of the manuscript to justify our choice of control intervention and the smaller number of sessions provided to that group. In addition, we are not able to change the control intervention at this stage as the trial has already commenced.

The new paragraph added to the discussion is also presented below:
“The absence of a placebo control, along with the different number of sessions that will be provided to the two groups, could be perceived as limitations of the trial. However, this will be a pragmatic RCT comparing our classification-based treatment protocols to advice in its usual clinical form. Advice is typically administered over 1-2 sessions [39-41], and in this form it is known to be effective [39-41] and recommended in all international LBD guidelines [38]. Other LBD trials that have involved a similar imbalance in the number of sessions delivered to each group have found no differences in outcomes [134-136]. It has also been shown that the placebo effect (in comparison to no treatment) typically accounts for only small standardised mean differences of around 0.3 for participant-reported pain outcomes, equivalent to 3.2-6.5 points on a 100 point pain scale [137-139]” (page 26).

Thank-you for the opportunity to submit a revised manuscript, and for the efforts and comments of the reviewer. I look forward to hearing from you in due course regarding the outcome of this revised submission.

Kind regards
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