Author's response to reviews

Title: A randomised controlled trial of preventive spinal manipulation with and without a home exercise program for patients with chronic neck pain.

Authors:

Johanne Martel (johanne.martel@uqtr.ca)
Claude Dugas (claude.dugas@uqtr.ca)
Jean-Daniel Dubois (jean-daniel.dubois@uqtr.ca)
Martin Descarreaux (martin.descarreaux@uqtr.ca)

Version: 4 Date: 27 October 2010

Author's response to reviews:

Dear M.Aulakh,

Please find included a revised version of the manuscript entitled "A randomised controlled trial of preventive spinal manipulation with and without a home exercise program for patients with chronic neck pain". All comments and suggestions made by the reviewers in the second round of revision were addressed and appropriate changes were made to the manuscript. These changes are highlighted in yellow. We would like to thank the reviewers for their helpful comments and we hope that these changes will satisfy the editorial board.

Sincerely,

Martin Descarreaux

RESPONSE TO REVIEWERS

A randomised controlled trial of preventive spinal manipulation with and without a home exercise program for patients with chronic neck pain.

Reviewer 1

Minor Essential Revisions

Comment 1

In the abstract, "HRQOL" appears without explanation.

Response: Appropriate changes have been made to the revised version of the manuscript.

Comment 2

Abstract: Result section should be written so that you report primarily if there was any difference between the three treatment groups AND you should include all
the outcome variables that you listed under method. Was there or was there not an effect?

Response: Appropriate changes have been made to the revised version of the manuscript.

Comment 3

Abstract: Results. Are you not saying the same thing twice about FABQ scores (second sentence) and at the end of sentence number three?

Response: The same result was reported twice. Appropriate changes have been made to the revised version of the manuscript.

Comment 4

Fig. 2 is very informative but it should run from minimum score to maximum score. For example if you use an eleven unit VAS scale, it should go from 0 to 10. Otherwise even small differences may look considerable. All three variables might have to be redrawn.

Response: The complete range of possible results is illustrated for each of the three outcomes.

Comment 5

On p. 9 you come with a brave statement, telling us about the clinically acceptable level. You have decided on an "arbitrary level". Fair enough, but is there no literature on that subject? What I am concerned about is that I do not find an explanation anywhere of the time limit for when they should note down their pain. That day or that week or what? Please specify.

Response: We believe that there is, at present time, no set value or threshold to define what is a good or bad prevention pain outcome. However, a 2 points (20%) difference in a VAS score is known to be a clinically significant difference. A few studies have documented the minimum clinically significant difference. This difference can be defined as the minimal clinical change that is meaningful for the patient following an intervention. Regarding VAS and pain, the minimum clinically significant difference was found to be 9 mm in one study. Differences of less than this amount, should therefore not be considered clinically relevant. Other studies showed that 13 mm on a VAS represents, on average, the minimum change in acute pain that is clinically significant.

Therefore, even though no precise threshold for “good prevention exist”, the 20% change in VAS is clinically relevant and the word arbitrary was taken out of the manuscript.

1: Kelly AM. Does the clinically significant difference in visual analog scale pain scores vary with gender, age, or cause of pain? Acad Emerg Med. 1998 Nov;5(11):1086-90.


Comment 6

I do not think that you can say in English that patients were "met" (you write this several times) when you mean that they attended the clinic/consulted. You should ask a native English speaking person. Also, you can dispense pills but it sounds very weird, at least to my ears, that you dispense chiropractic consultations and suchlike.

Patients came back for "treatment". Well the control group did not get a treatment so perhaps rather write "visit", "appointment" or suchlike.

Response: A suggested and upon further consultation the expression “met” was replaced in the text.

Discretionary revisions

Comment 1

Method, p.7 last sentence in third para: Perhaps add the word “future” in "...blinded to treatment allocation for the FUTURE preventve phase"

Response: Appropriate changes have been made to the revised version of the manuscript.

Comment 2

When presenting results as mean improvement it would be nice to know what, for example, the maximum possible value is. E.g #"...the average pain level of participants decreased by 1.2 cm out of 10 on the VAS".

Response: The full range of possible values are now included in the figures.

Comment 3

Please supply reference for statement on clinical significance thresholds that have been proposed (top of p.13).

Response: Appropriate references have been added.

Comment 4

P.13 I do not understand on whom you report overall compliance ("excluding the patients who dropped out during the randomized phase of the trial". If you exclude these how can you talk about compliance? Perhaps explain more
clearly.

Response: Drop outs and compliance are different statistics in this study. Compliance refers to the attendance of each participant to his specific treatment regimen (number of visit out off the total possible visits).

Comment 5

Discussion first para. I see you talk about what went well but not what did not work. Your study is about comparing three preventive strategies. Get the wool out of your mouth and say it clearly so that everybody can understand. Is there a difference in outcome when you perform SMT with or without home exercises? Does this strategy seem to work or not?

Response: The wool was taken out and appropriate changes were made to the discussion section of the manuscript.

Reviewer 2

Major Compulsory Revisions

Comment 1

On page 13 - clinically acceptable pain: the authors should define what level of pain was chosen. (acknowledged that this reviewer suggested 3.0)

Response: In the first revision the previous comment was taken into consideration for the calculation of number of patient with clinically acceptable pain. To reflect the “tertiary prevention” component of the trial it was decided, as stated in the methods section to calculate the number of patients that stayed below a level of clinically acceptable pain (2 point difference from baseline value).

Comment 2

The authors should give both n, and percent for the cut point chosen and they should also give the time point or points that this was determined.

Response: Appropriate changes have been made to the revised version of the manuscript.

Comment 3

it needs to be clear on page 14 what is represented by the 7.6+/-.1.1 co-interventions compared to the other two groups (4.1+/-.0.9 and 2.9+/-.0.9). What does 7.6 represent ? 7.6 “episodes” of co-intervention ? days of co-intervention use ? doses ? etc.

it is stated that it is significantly different. is this statistically significant, in which case a post hoc p-value would be useful, or it is meant that this is clinically important ?
Response: The assessment of co-interventions was clarified in the methods and results sections of the revised manuscript. The differences statistically different and p values are now indicated in the results section.

Comment 4

How do the authors know that they applied the "right dose" of SMT over the 10 weeks of study. this should be acknowledged as a limitation, if there is no clear data-driven basis for the selection of the 4 sessions.

Response:. This limitation is now acknowledged in the discussion section of the revised manuscript.

Minor Essential Revisions

Comment 5

a. Table 3.

Need to add SD to the table. while it is acknowledged that one can use the 95%CL to back calculate the SD, SD is preferred to 95% CI. Also, as authors know well, overlap of 95% CI is not the same thing as differences between groups based on a p-value from ANOVA. No objection to presenting both SD and 95%CI.

Response: Appropriate changes have been made to the revised version of table 3 and 4.

Reviewer 3

No comment from this reviewer needs to be addressed.