Author's response to reviews

Title: Effect of spinal manipulation on sensorimotor functions in back pain patients: protocol for a randomized clinical trial

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Version: 2 Date: 1 June 2011

Author's response to reviews: see over
June 1, 2011

Dear Editors-in-Chief,

I am pleased to resubmit the revised manuscript “Effect of spinal manipulation on sensorimotor functions in back pain patients: protocol for a randomized clinical trial” to Trials.

I and the other authors would like to sincerely thank the reviewer for his tremendous time and attention to this manuscript. Not only is the paper much stronger because of his comments, but he also pointed out errors that we were thankfully able to correct prior to publication.

In the reviewer comments listed below I addressed each concern on a point-by-point basis. Please let me know if I can provide any additional information as you consider publication of this manuscript.

Sincerely,

Christine M. Goertz, DC, PhD
Palmer Center for Chiropractic Research
Version: 1 Date: 3 May 2011
Reviewer: Charlie Goldsmith
Reviewer’s report:
Comments to the authors:
1. P(age) 1, l(ine) 11. Since all the authors have contributed equally to this work, was the order of the author listing randomized? If so, state it.

While each authors’ contribution to this manuscript was substantial, the order is not random. The line regarding equal contribution has been erased and authors’ individual contributions are listed in the “Author Contribution” section.

2. P 3, p(aragraph) 3, l 1. Please provide the date of registration, the date the first patient was randomized and the date of last patient entry if these are currently known.

This information was added.

3. P 4, p 1, l 3. Replace [ranges] by [vary] twice. A range is the length of the interval and so you have shown intervals of prevalence and not their lengths. Consequently vary is a better verb.

Replaced as recommended.

4. P 4, p 1, l 4. Insert [patients with] between [of] and [LBP].

Inserted as recommended.

5. P 4, p 2, l 1. In what sense is [significant] used here? If it is statistical, insert [statistically] in front of it; if it is a clinical or content judgment, then replace it by another word such as [importance].

Replaced as recommended.

6. P 4, p 2, l 3. Suggest rewording as [This study looks closely …]. You do not justify that the approach is yours alone.

Reworded as recommended.

7. P 5, p 1, l 8,9. Provide references to the terms [adjustment] and [manipulation].

References provided as recommended.

8. P 5, p 2, l 1. Suggest rewording such as [The general theory …].

Reworded as recommended.
9. P 5, p 2, l 3. Suggest rewording such as [… time, this study considers the nature …].
Reworded as recommended.

Reworded as recommended.

Replaced as recommended.

Replaced as recommended.

13. P 6, p 3, l 1. Suggest replacing [significant] by [important].
Replaced as recommended.

Replaced as recommended.

15. P 7, p 2, l 1. Suggest rewording as [… to healthy individuals]. You do not know the population values.
Reworded as recommended.

Inserted as recommended.

17. P 11, p 4, l 5. Why is the weight 306 here while it is 307 on P 39. Is this the same as 140 kg? Is there a rationale?
Language has been changed to be consistent (> 307 lbs). The rational is that there are safety concerns related to equipment weight capacity.
18. P 12, p 1, l 8. Since [or] logically includes [and], suggest dropping [and/]. Also
P 40, l 1.

Reworded as recommended.

19. P 15, p 2, l 1. Who wrote the code for this? It is not mentioned in reference
72. How was it validated?

The manuscript has been revised to indicate that a web programmer wrote the
minimization code based on Taves’ method and the code was tested and validated by a
data manager.

20. P 15, p 2, l 4. Insert a space to read [< 4].

Inserted as recommended.

21. P 16, p 1. How can this be? You claim you are using minimization and that is
determined be the way the patients enter the study. Envelopes cannot be
prepared in advance and sequentially numbered. Please explain really what is
intended.

The manuscript has been revised to explain that the envelopes were a back-up method
in case the web system was unavailable, such as a server failure. Therefore, if a
participant was allocated via envelope, the participant was not allocated according to
the minimization algorithm. However, the data were entered into the web system after
allocation and subsequent allocations did take that participant’s data and treatment
group allocation into account. Participants were allocated by envelope in 2/221
allocations for this trial.

22. P 16, p 2, last 3 lines. Please provide a reference to this.

Provided as recommended.

23. P 17, p 1. Provide a reference to this.

Provided as recommended.

24. P 17, p 2, l 2. Rewrite as [30 N].

Rewritten as recommended.

25. P 17, p 2, l 7. Provide a source for the activators.

Provided as recommended.
26. P 18, p 1. Provide a reference to this.

Provided as recommended.

27. P 18, p 3, l 6. Presumably this means without shoes and not the rest of their clothing!

Rewritten as recommended.


Rewritten as recommended.

29. P 19, p 1, l 7,8. Is flare angle a factor in the readings? Is there a reference that it is or is not important?

Flare angle was recorded due to concerns that foot orientation may influence standing posture stability (Rougier, 2008) or compensate for trunk fatigue (Parnianpour et al, 1988). References have been added to the manuscript.

30. P 19, p 2, l 3. Provide a source for these devices.

Provided as recommended.

31. P 20, p 1, l 12. How is the randomization done?

The manuscript has been modified to explain that random permuted blocks for the 6 testing sequences were prepared by the web programmer and stored in the web system. The biomechanical objective examiners were blinded to upcoming testing sequences.

32. P 20, p 2, l 6. Suggest rewriting as [… move within their comfort range.].

Rewritten as recommended.

33. P 21, p 1, l 9. Provide a source for this device.

Provided on page 19.

34. P 21, p 2, l 3,4. Is there a reference to this equation?

This equation was empirically derived based upon the minimal drop height that yielded an EMG response in previous unpublished pilot work. It is a best fit linear regression equation relating the drop distance to height and weight of study participants.
35. P 23, p 1. Describe the minimum clinically important difference (MCID) and scoring boundaries as well the interpretation for all the measurement scales. Specific measurement properties should be stated if they will be used in the study.

MCID for RMDQ is from 2 to 3 points. This information and a reference were added.

36. P 23, p 2. Please state and reference the MCID. Also P 23, p 3.

While MCID is available for some versions of LBP bothersomeness scales, we are not aware of a MCID for the instrument we used.

37. P 23, p 4. Which version will be used? Since there are 10 measures each with possibly different MCIDs, which will be used?

SR-36, version 2 was used in the study. This information was added to the manuscript. Physical function and bodily pain measures are the primary measures of interest. This information, with referenced MCID, was also added.

38. P 24, p 2, should state the MCID and metric properties.

We do not plan to use patient satisfaction as an outcome measurement and have removed this section from the manuscript.

39. P 25, p 1, l2. Was a fax data entry system considered? What are the measurement properties of the data entry?

A fax data entry system was not considered. Paper data collection forms are only used for participant self-report data. We developed our double key-entry verification software programs and procedures over 10 years ago. We follow documented standardized data collection and handling processes. Our quality control procedures include double data entry with blind verification and programmed range and consistency checks. We have researched purchasing optical character recognition software and hardware and to date have not found it to be cost effective in our setting.

40. P 27, p 2. References are needed for all these systems of dealing with AEs.

Source provided as recommended.

41. P 27, p 2, l 7. Suggest replacing [significant] by [clinically important].

Replaced as recommended.
42. P 28, p 1. The calculation here should have been $63/0.85 = 74.1$ or 75 rather than $1.15(63) = 72.45$ or 73. Was a software package used to derive the 63 per groups? (Reference it). What are the other values assumed for this sample size? Were the 4 minimisation factors included?

Thank you for pointing out this error in the sample size calculation. Fortunately, our dropout rate was approximately 5% and there is very little missing data in our postural sway measures. Software package added. The minimization factors were not considered in the sample size calculation.

43. P 28, p 2, l 5. Suggest rewording as [Table 3 presents a variety of power values for these variables.].

Reworded as recommended.

44. P 28, p 4. Doing a 1-way ANOVA suggests that you have not considered the 4 minimization factors in your analysis.

We are planning on adjusting for the minimization factors in our analysis and have modified that section in the manuscript. Thank you for pointing out that we neglected to include this information.

45. P 29, p 1. These is no need to do a preliminary F test; you could do directly to doing the 2 pre-planned tests using Dunnett's test. Otherwise this is a conditional analysis.

There are differing opinions regarding whether or not pre-planned tests should be conducted based on the overall F-test. However, we agree that it is unnecessary in this case.

46. P 29, p 1, l 3. Replace [a] by [#].

Replaced as recommended.

47. P 29, p 1, l 4. Those selected should be pre-specified, such as the minimization factors in all analyses and any others that be identified at baseline. The validity of these ANCOVAs should be checked.

The minimization factors and validity checks have been added to the manuscript.

48. P 29, p 3. Comparison between the groups should also be shown, otherwise why collect the data. It is the interpretation that matters.

We agree and have modified the section as such.
49. P 29, p 4, l 2. Which of the 10 subscales will be used?

Physical function and bodily pain have been added.

50. P 30. There should be a mention of the software to be used to do these analyses and how will missing data be handled?

Both have been added on page 29.

This reviewer took a random sample of 10 R(eferenices) to check accuracy of citation. The results with selected others are shown next. This reviewer also likes to report the journal issue number as it makes it easier to find the R when wanted.

The style was updated to include issue numbers and all authors.


52. P 32, R 12, l2. Insert [(1)] after [30]. Inserted.

53. P 33, R 24, l 1. Insert [(3 Suppl 1)] after [85]. Inserted.

54. P 34, R 28 l 1. The fourth author is [van Meshelen W], and on l 3 insert [(1-2)] after [130]. Fourth author name is fixed and issue inserted.


57. P 35, R 44, l 3. should be [2011;23(3):358-368.]. Fixed


59. P 35, R 51. Trials likes to publish ALL authors so replace [et al] by the rest. Also P 37, R 74, l 1. All inserted.

60. P 37, R 72, l 3. Insert [(6)] after [23]. Inserted.

61. P 37, R 76, l 2. Insert [(11)] after [78]. Inserted.


63. P 38, R 82, l 1. Rewrite first author as [Ware JE Jr.], on l 2 rewrite as [Manual] and on l 3 rewrite as […] Center. QualityMetric Inc. Lincoln RI, 1993.]

Fixed.
64. P 38. While there are some short forms defined at the bottom of Table 1, there should be a complete list of all used in the article. Many are not listed in Table 1.

List of abbreviations provided on page 32


Added as recommended.

66. P 42. What is the source for the MCID used in these power calculations?

To our knowledge MCID’s have not yet been defined for these biomechanical variables. We powered our study based on the findings of Hamaoui (reference 94) and Leinonen (reference 47). Hamaoui et al. found an excursion difference between the control and the low back pain population of 1.0 mm and 0.5 mm in anterior-posterior (X) and side-to-side (Y) directions, respectively. Leinonen et al. found a sway speed difference between the control group and the low back pain participants to be approximately 4 mm/sec.

67. P 43, centre box 4 at the bottom should convert the allocation to ® to show that it is randomized.

Changed as recommended.