Reviewer's report

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

**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.

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.

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.

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

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].

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

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

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

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


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


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


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?

18. P 12, p 1, l 8. Since [or] logically includes [and], suggest dropping [and/]. Also
19. P 15, p 2, l 1. Who wrote the code for this? It is not mentioned in reference 72. How was it validated?

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

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.

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

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

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

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

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

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


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?

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

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

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

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

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

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.

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

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

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

39. P 25, p 1, l 2. Was a fax data entry system considered? What are the measurement properties of the data entry?

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

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

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

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

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.

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

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.

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

49. P 29, p 4, l 2. Which of the 10 subscales will be used?

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?

This reviewer took a random sample of 10 R(efernce)s 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.


52. P 32, R 12, l 2. Insert [(1)] after [30].

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

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


56. P 35, R 41, l 3. Insert [(22)] after [21].

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


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.

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

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


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.
66. P 42. What is the source for the MCID used in these power calculations?
67. P 43, centre box 4 at the bottom should convert the allocation to ® to show that it is randomized.