Reviewer’s report

Title: Effects of spinal manipulative therapy biomechanical parameters on clinical and biomechanical outcomes of participants with chronic thoracic pain: a randomized controlled experimental trial

Version: 0 Date: 11 Nov 2018

Reviewer: Erik Poulsen

Reviewer's report:

Dear Editor,

Thank you for the opportunity to review this manuscript.

I congratulate the authors for conducting a randomized controlled trial (RCT) of important scientific and clinical value. Unfortunately, the RCT is not reported according to current recommendations. Further, very little emphasis is included discussing the relatively important finding of none of the three experimental groups demonstrate differences in outcomes in comparison to the forth control group not receiving SMT. Please see comments below and I suggest authors to follow the CONSORT 2010 updated guideline for reporting parallel group randomized trials (David Moher et al. Journal of Clinical Epidemiology 2010;63:e1-e37).

There are some discrepancies between the protocol registered in Clinicaltrials.gov and the manuscript. The title states an evaluation of how SMT dose modulate spinal stiffness. If that is the case, the primary outcome in the study should be spinal stiffness and not pain and disability as listed in the paper. Please clarify and revise accordingly.

The primary purpose of an RCT is to compare different interventions in groups expecting baseline values to similar in all groups. That way the only difference is the interventions between groups. Therefore, the finding of no difference between groups is highly relevant.

Please include a CONSORT checklist as recommended by the CONSORT statement.

Title: consider using the term quasi-randomized as the allocation process is not performed according to CONSORT recommendations.

ABSTRACT

Methods: Here authors mention four sessions - this is confusing for the reader when they write three in the Background section.
The eighty-one adults belong in the Result section. Which type of participants recruited and included is relevant in the Method section.

Consider rephrasing the sentence of primary outcomes as spinal stiffness is mention first (secondary outcome).

Recommend authors to mention which disability and pain scales.

When was between-group differences assessed? Every week or only at follow-up. Please include.

The finding first mentioned in the Result section is the with-in group difference. Please include this in the Method section (e.g. With-in and between group differences …….)

Results:

Please include actual numbers of the primary outcomes and 95% confidence intervals for differences between groups. In an RCT the observed differences between groups are the main finding. See Moher et al. 2010 CONSORT.

The last sentence can be avoided as it is a tertiary outcome and one patient out of 81 is to be expected.

MAIN TEXT

BACKGROUND:

Overall, a well structured section, proper length, relevant story flow and easy to follow.

Line 47-48: Please cite this first sentence with one or two references.

Line 53-55: Is the force only delivered to the intervertebral articulation? Is this not an old way of looking at SMT where the manual force is transmitted through to a broader area? Is it possible only to influence just the articulation and not the surrounding soft tissue structures? Consider elaborating.

Line 58: authors cite six papers which all include the last author of this paper. It appears the senior author is trying to inflate his citation index. Consider including only 2-4 citations with is enough to cite the issue raised.

Line 73-75: The sentence indicate frequency/number of treatments is not a 'true' dose. Further, what does authors consider a 'true' dose? Please revise.
Line 75-80: Please consider placing the citation after the first sentence and mention early to the reader that Snodgrass et al. is and RCT. This will guide the reader to the last sentence regarding their finding. To further assist the reader, please also briefly mention what primary outcome the RCT compare.

METHODS

What effort has the authors done to secure a high enough number of participants in each group to find a clinical relevant difference between groups? I cannot find any mentioning of sample size calculation or why this is not relevant. Please include.

How relevant is it that all patients are receiving treatment in exactly the same area and how does that correlate with clinical practice? Please elaborate and consider including in section of Study Limitations.

If the primary outcome is disability and pain intensity, why does authors primarily concentrate on reporting and discussing the secondary outcomes? Please elaborate.

Line 93: As in the abstract, how many patient were included in the study belong in the Result section. Description of population and recruitment is important here. Consider revising.

Line 100-102: This sentence is confusing. Was the first three sessions identical in all four groups?

Line 102-103: Please state the inclusion and exclusion criteria.

Line 104: If the envelope is pre-identified, then it appears the randomization is not random? Consider naming it a quasi-randomized controlled trial. Possibly check with the CONSORT statement.

Line 103-107: This type of randomization is not in accordance with the CONSORT statement. I suggest the authors follow-up this and at least cite the CONSORT.

Line 112: why is lying face down for 30 minutes important? Please clarify.
Line 112-119: Did all participants in the experimental groups receive SMT at T7? What clinical indications were in place for all participants to receive SMT at T7? Please clarify.

OUTCOMES

Line 124-41: To assist the reader, consider including a table of outcomes and at which time points they are evaluated.

Why are spinal stiffness and eEMG not listed under Outcomes?

Line 225: This is the first time authors mention 'primary outcome'. Please follow the reporting suggested by CONSORT.

Line 236: Please again follow the suggested reporting by CONSORT. Also consider citing the use of CONSORT.

RESULTS

Overall, the language used in the whole section is mostly for scientist. Consider revising for a broader audience including clinicians.

Table 1: authors need to explain and interpret why the average pain for the control group is more than twice as high as Dose groups 1 and 2 and 2/3 higher than Dose group 3.

Line 265-267: Average pain. See my comment above. So if the control group is 150% higher than Dose group 1, is the difference not statistical significant? Same for comparison between control group and Dose group 3 with a difference of 67%.

Line 273-282: It is common to present the results of the primary outcome initially after the descriptive / baseline characteristics. Consider revising.

Line 274: The statistical tests are already mentioned in the methods section. Please review a few high quality RCTs and consult the CONSORT statement on reporting so it is in line with current recommendations.
Line 288: Please see comment for line 274.

Line 298-299 and Figure 5: The histograms are not easy to interpret. Consider plotting the two primary outcomes for the 4 time points in one or two graphs.

Line 301-305: So just because no group effects are observed, why then present the clinical variables and spinal stiffness. This is not in accordance with recommended reporting (CONSORT).

Line 291-92: Please see comment for line 274.

Line 308, 313, 320: Please see comments line 274.

Line 332-52: This whole section is very little reader friendly. Consider revising for an audience including clinicians. Only scientists with an understanding of the performed analyses will know what it means.

Line 341: Again, consider rephrasing the first sentence, as very few readers will understand: 'Analysis revealed greater slopes of change …. The explanation in the parenthesis does not help much.

Line 346-347: How an analysis is performed belong in the statistical section and should not be repeated. Please revise.

**TABLE 1**

For average pain and pain intensity, please indicate the scale. Further, it is not clear to the reader what the difference is between the two.

All abbreviations in a Table should be explained below the Table.

Please include 95% confidence intervals and not p values for statistical significance.

The footnote indicate mean pain levels at baseline only is significant higher in the Control group than in Dose 2 group. The mean in group 1 and 2 are the same. Further, the mean in the Control
group is more than 100% higher than group 1 and 2 and 67% higher than group 3. Please explain and how this will influence results when no adjustment is done for baseline differences.

DISCUSSION

Line 357-58: This first sentence is repetitious from prior sections. Consider deleting.

Line 369: 'these participants' refer to which group(s)? Please clarify.

Line 370-71: 'control group' - please be consistent in naming the groups. If it refers to the placebo group, use the same name label consistently.

Line 372-75: Authors state the results by Snodgrass et al. are 'elusive'. If they find an effect of mobilization (90 N), how can that be elusive? It seems, if they observe an effect how can that be consistent with an absence of a strong influence of SMT characteristics? The argument that this is in accordance with the results of this study is poorly justified.

Line 376-77: 'distinct' - usage of adjectives in academic writing is not commonly used. Here it appears the authors are trying to raise the study to an inappropriate level. Further, the aim of the current study was also looking at the patient reported outcomes, so the neuromechanical effects are not distinct. Please revise.

Line 380: a study/paper not fully published should not be cited, as readers have no chance of verifying the claims made. Please revise.

Line 392-393: Why study a wider range of SMT doses when the control group demonstrated the same results as the three experimental groups? It would be more important to investigate why the control group obtained the same results as the other three groups. In this study, there is very little evidence that another SMT dose can optimize clinical improvement. This is supported by the authors in line 394-96.

Line 408-409: If no effect is observed differently than from a control group, why would it be necessary to determine a MCID in spinal stiffness? Absolutely no reason to conduct a study examining this.
Since the authors include a control group receiving no SMT, it is likely no subgroups exists. Please include this in the discussion.

Authors also need to discuss the improvement observed in the control group. It appears the authors more or less ignore the improvement in this group when discussion the findings of this study.

This is the first time authors mention the possibility of contextual effects being responsible for observed clinical effects from SMT. The purpose of an RCT is specifically to compare interventions and the primary focus should be to comment of the non-observed differences between groups and possible explanations for this.

STRENGTHS AND LIMITATIONS

I do not agree with authors regarding the main strength of the study. The main strength must be the comparison between groups using a randomization sequence to minimize differences between groups. That is the purpose of doing an RCT.

Previously in the paper, authors mention they have selected the three doses to replicate the forces applied in clinical practice. Therefore, the selected three doses are not a limitation of the study.

Please discuss the limitation of this is not a clinical setting where all patients receive the same SMT administered to the same area.

Authors need to discuss the important preliminary finding that no relevant differences are observed between the four groups in regard to any of the important outcomes. This has significant implications for understanding the effect of SMT and the effect observed in a clinical setting in likely contextual and has very little to do with the force and mechanical application of either a mechanical device. The result of this study support this.

CONCLUSION

The main conclusion of the trial is that there is no difference between groups regarding the primary outcomes. Please include this in the first sentence.
Line 460-462: Again, include that the same decrease in primary outcomes were observed in all four groups.

Line 463-64: The last sentence is not supported by the study.

REFERENCES

Including 52 references in a study of this type is excessive. Please revise.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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