Review of manuscript: 'Manual cervical distraction for neck pain: results of a pilot randomized controlled trial'

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Thank you for the opportunity to review this interesting study investigating a treatment approach for the management of chronic neck pain. While this is a very thorough report, I think it could be written much more succinctly to bring out the important points more clearly. It reads more like a thesis because of the level of detail in some areas eg ethical procedures, yet some other areas are lacking attention to detail. One major point which is of concern is the lack of a proper control group given this is described as a randomised controlled trial. In particular given the variable course of neck pain with exacerbations and remissions it is important to have a control with no treatment. While I appreciate the authors attempts to provide a credible minimal intervention I think this is problematic since any hands-on intervention in a sensitive area such as the cervical spine is quite likely to have some therapeutic effect.

The other main concern is the length of the report and lack of clear research questions which can be followed through the methods and results and discussed in the discussion section.

I have added some comments in the various sections, shown below.

MAJOR COMPULSORY REVISIONS

1. Research question is not clearly highlighted. This needs to be outlined at the end of the introduction

2. Methodology seems to be very wordy and could be expressed more succinctly. I could not find an indication of formal word count for the manuscript on the instructions to authors. A more focussed report would be easier to read and highlight the main features more clearly.

3. Statistical methods

No analysis seems to have been done comparing participant characteristics between groups- seems this is important as there were some obvious differences between groups some of which you report in results.

4. Figure 1.
Methods state participants wore a collarless shirt, patient has a collar on. Extremely difficult to see the set up due to clothing and the box! Box entirely obscures the set-up. ? is this needed as patient is adequately concealed by prone positioning. Would be much better illustrated with a model with dark close fitting clothing and low neck line or shirt off? Also consider using a female participant since the majority of patients were females.

MINOR COMPULSORY REVISIONS

INTRODUCTION
1. Add dates or a reference when report names of authors who have done studies. Eg Chiu and colleagues (date)…..
2. I think it is worth saying that traction has been evaluated but not traction in prone?

METHODS

Ethics.
3. A lot of detail is provided on the ethical process, is this necessary?

Sample size
4. How has this been justified? Study is described as a pilot study so this issue may be addressed in the main study but useful to include here.

Inclusion/exclusion
5. Might be easier to read inclusion/exclusion criteria as a list. Not justification for all things, inconsistent reporting of rationale for exclusion
6. Presumably chose older females because this is the most common group reporting neck pain useful to mention this.
7. Give reason why excluded pts with nerve root pain as you have done for high pain levels. You include pain with radiating symptoms but you exclude those with nerve root? Why? need to include for example that this was due to safety concerns.

Intervention
8. Participants lay prone on bed, with their head on the moveable headpiece. Were they strapped to it? how did the head stay there? Need to provide detail
9. Given the differing shapes of the female anatomy were any modifications to positioning made to accommodate different female chest shapes and bust size which might have altered the angle of distraction force?

Measurements
10. 1st para change word ‘participant expectancies’ to expectations
11. Include units in brackets after each outcome measure
12. ? leave out details of electromyography if not reporting results here.

Participant eligibility and recruitment
13. Consistency in VAS scale: in VAS 11point scale is used, patient reported
outcomes 100 point scale reported
14. Record the anchors for scales in a consistent way. Eg Participant satisfaction
NRS, record as for previous measures: 1 not at all satisfied, 10 etc etc

Setting
15. Hertz should be recorded as Hz. Is it necessary to provide meaning of hertz?
16. ASCII file- not explained
17. Last sentence give units eg Average peak force (units) ..... Credibility and expectancy questionnaire
18. No clinometric data given for CEQ
Qualitative interviews
19. Include here that interviewer was blinded
Blinding protocol
20. 1st Para (line 7) typographical error ‘blending’ should be ‘blinding’

RESULTS
21. The primary and secondary outcomes should be Reason for drop outs?
If they had previous chiropractic care for this episode was this an exclusion? This
might have affected the results. Needs to be explicitly stated that they did not
have other prior treatment.
22. Participant numbers do not add up. Flow chart does not unfortunately show
up on the website, this might help explain this. It appears that a very high
numbers of participants were excluded or chose not to participate. Reasons that
109 chose not to participate were not given, does this bias the group?
23. Statistical comparison between groups would have been useful eg. looks like
high force traction group had less pain
24. Methods say eligibility had VAS on an 11 point scale, here it seems to be
reported on a 100 point scale.
25. Variable course of neck pain, over 5 week period might be expected to
improve due to time. Consider using a non-treatment based control as well.
26. Variation in traction force noted by the researchers makes this difficult to
evaluate different force groups. Adding feedback is useful but limits the results
prior to the introduction of this.
27. Lack of a control group, variable course of neck pain make it difficult to know
if treatment helps or would have got better anyway. Minimal force still has hands
on and some traction force through the neck so some therapeutic effect cannot
be discounted altogether. Participants will still have some sensory input which
may be enough to stimulate some spinal gating.

DISCUSSION
28. The discussion is well written but is limited by the lack of a clear research
question from the start.
29. There are some outcomes such as improvement in sleep or fatigue which are discussed which were not mentioned in the methods or results and for which the relevance to this study is unclear.

30. There do seem to be a high number of adverse events which, even if mild or moderate detract somewhat from the improvements in VAS and NDI.

TABLES/FIGURES

31. Flow diagram as per CONSORT guidelines would be helpful, did not show up in manuscript

32. A separate figure showing headpiece would be useful.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests