Reviewer’s report

Title: Manual cervical distraction for neck pain: results of a pilot randomized controlled trial

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Reviewer: Martin Descarreaux

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Title: Manual cervical distraction for neck pain: results of a pilot randomized controlled trial

General comments

The manuscript describes the results from a Pilot RCT and focuses on clinical as well as feasibility data. The manuscript is well constructed and I believe that a few changes to the introduction and discussion would improve the readers’ understanding of the proposed study. I have assessed the manuscript using the 2010 CONSORT checklist and I have also added, when relevant, specific comments related to “non-methodological” issues. I have identified a few issues in the methods section that I believe can be easily addressed by the authors. At this stage the only concern I have is that the targeted clinical population is not clearly identified.

MAJOR COMPULSORY REVISIONS

Comment 1

The introduction clearly describes the current state of knowledge with regard to cervical traction. However, mixing populations of patients such as whiplash-patients, patients with radiculopathy and common neck pain patients to document the efficacy of cervical traction is somehow misleading. The introduction should clearly identify a knowledge gap related to the clinical population of interest, and specify how and why this population and the intervention should be further studied.

Comment 2

The use of minimal intervention (low force traction) should be better justified. Perhaps a clear objective and the related hypothesis would clarify this issue.

Comment 3

On page 6: The second part of the first paragraph describes “mechanistic evidence” related to manual therapy but not specifically to cervical traction. The referenced studies relate to low back pain and other types of manual therapies which I find quite different from the traction intervention proposed in the current study (especially from a mechanistic standpoint). I would suggest deleting this section which does not add much to the intro.

I also find the last paragraph on page 6 to be not very useful and I would suggest
the authors move the information (when relevant) to the related sections of the methods/discussion. For instance, the various forces and the related references could be presented in the intervention paragraph. In other instances it could simply be deleted from the intro.

Comment 4
Sample size should be justified or explained even if one of the goal was to generate data for future sample size calculations.

Comment 5
Please define neck related upper extremity pain and provide a reference is possible. I am not sure why the whiplash Quebec task force was used? Were there only traumatic neck pain patients recruited? Why not use the more recent classification proposed by the 2008 Neck pain task force. Please clearly identify the target population (clinical condition, Diagnosis, etc), the inclusion criteria. Perhaps a table presenting inclusion and exclusion criteria would clarify the issue.

Comment 6
Clarifications with regards to researcher and staff involvement are needed. Who performed the assessments, who performed and supervised treatments, who performed statistical analyses?

I commend the authors for the thorough description of the interventions.

Comment 7
The authors should better explain the rational for the chosen forces? I know that they have conducted various preliminary studies but the rational for these forces is still not clear to me. Is there an underlying dose-response hypothesis, is it a safety issue, is more force believed to be better than lesser forces or are we simply looking for a credible sham procedure. This is partly addressed in the discussion but should be stated earlier in the paper.

Comment 8
Baseline characteristics should be compared across group for statistical differences. It should be clearly reported in the text or in the table. There seems to be possible significant differences for quite a few variables (age, current pain, BMI, type of neck pain).

Comment 9
The first sections of the discussion seems to provide contradictory arguments in favor of manual cervical distraction. On the one hand the authors specify that manual distraction allows clinician to adapt to sensation and patient’s comfort and tolerance but on the other hand they propose that real-time biofeedback enables standardization of treatment delivery. Although treatment delivery in manual therapy remains a “research challenge”, is it something that would improve clinical efficacy? Would not patient tolerance and preferences be the clinical priority? The lack of clear objective and hypothesis does not help understanding the main goal of the researchers. It is only later in the discussion that the design of a credible sham procedure was one of the goal of the study. I
believe that should be stated earlier in the manuscript.

Comment 10
The sample of participants involved in the study seems to be a mixed (or potentially mixed) population of patients with neck pain. As per neck pain task force 2008, patients with whiplash related neck pain, common neck pain and other types of neck pain should not be considered as a homogenous population. I believe that this should be addressed by the authors, and considered in the planning of a larger study.

MINOR ESSENTIAL REVISIONS
Comment 1
The title adequately describes the study and the chosen design. The “force-based minimal intervention” is mentioned in the abstract but only defined later in the methodology. I don’t believe that most clinician or researcher in the field would be aware of what constitute a “force-based minimal intervention”. It should either be defined or simply presented as a control or sham intervention (it all depends on the objective). The description in the methods section of the abstract adds to the confusion since the study arms are presented as 3 different active treatments where various levels of force are used. The lack of a clear objective and hypothesis also contributes to the confusion.

Comment 2
I am not sure why the authors state that “there are no published clinical trials evaluating the efficacy of this therapy”. There seems to be distinctions between interventions or design that I have not understood since the authors, prior to such statement have clearly highlighted a large body of scientific evidences related to cervical traction. Do they consider manual traction to be significantly different from other types of traction or is there an important methodological flaw that has never been addressed in prior studies? Again the justification is presented in the discussion rather than the intro.

Comment 3
There are a few minor, but important information regarding randomization that should be included in the manuscript: Who generated the random sequence and performed randomization, who assigned participants and was there any concealment strategy prior to assignment.

Comment 4
Once defined, abbreviations and acronyms should be used throughout the text (ex. “Baseline 2” on page 16).

Comment 5
Was an intention to treat analysis conducted and if so what strategy was used.

Comment 6
A graph illustrating the raw changes in primary outcomes should be included.

Comment 7
The important number of dropouts for the interview should be further discussed in light of future trials (is it relevant to conduct such interview, are there other possibilities).

Comment 8
Can you provide a reference for this sentence (discussion): MCD is a traction-based treatment for cervical and thoracic spine pain and dysfunction that is commonly delivered by doctors of chiropractic? I am not sure this reflects current practices in other parts of the world.

Comment 9
I am not that recruiting 5 patients per months should be interpreted as high interest in the trial. Perhaps limitations of the recruitment plan should be further addressed.

DISCRETIONARY REVISIONS
Comment 1
The text switches from passive to active tense (we). Although, I personally prefer the passive tense, the authors should at least consider standardizing the use of verb tense.

Comment 2
Figure 1 does not add much information.

Martin Descarreaux

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests