Reviewer's report

Title: The effectiveness of motorized lumbar traction in the management of lumbo sacral nerve root pain: A pragmatic randomised controlled trial

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Reviewer: Julie Fritz

Reviewer's report:

General

The authors of this study examine an important topic, the effectiveness of lumbar traction in more specific sub-group of patients with LBP (those with sciatica and signs of nerve root compression). As the authors point out in the Introduction, there is a lack of research using appropriate methodology to examine lumbar traction for these patients. The methodological issues of the current manuscript, however, raise the concern that the present study may only contribute greater confusion in the literature. These concerns are outlined below:

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. A major concern about this manuscript is the small sample size. The study is substantially under-powered to detect minimally important differences on the primary outcome measures. The authors portray the study as a “feasibility” study, however they proceed to report inferential statistics examining between-group differences. With the potential for Type II error so high, this could lead to conclusions about the effectiveness of the interventions that may be potentially misleading and erroneous. If the authors truly conceive of this project as a feasibility assessment, the results should be reported in more descriptive, less inferential terms.

2. The authors perform a post-hoc power analysis and suggest that an appropriately-powered trial would not be possible. The key consideration, however, is not how many patients would make the difference estimated by this study reach statistical significance, but how many patients would be required to detect a minimally important difference if one did actually exist. There is a substantial body of literature documenting the MCID for the Roland Morris and VAS that would support appropriate powering of a study such as this. The paragraph on page 11 describing the post hoc power analysis should be removed. If an a priori power calculation was performed it should be described. If not, I recommend removing the between-group inferential statistical analyses as suggested above.

4. Page 3 – The objectives of the study need to be consistent with the methods actually used. If the authors intend to examine feasibility, reporting inferential between-group statistics should be avoided. Also, appropriate sample size should be determined a priori based on meaningful differences, not post-hoc based on the difference estimated from a very small sample of patients.

5. Table 2, It appears that there may be baseline differences between the groups that are important, even though they did not reach statistical significance. This is not surprising given the small sample size. For example, 25% of the traction group was off work compared to 43% of manual therapy group. 81% of patients in the traction group do not appear to have had prior episodes of LBP compared to 36% in the manual therapy group. 63% of traction group participated in physical activity compared to 36% in manual therapy group. These differences have the potential to introduce bias into the results. The authors do not attempt to adjust for any of these differences in the analysis.

6. Drop-outs and compliance were an important consideration. Examining Fig 2 it appears that 77% of subjects originally randomized were included in the analysis. It does not appear that intention-to-treat principles were used in the analysis. This introduces another important potential source of bias in the results.
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Do not use bulleted lists in the text (page 3-4). Either place this information into a table or describe it in sentence format.

2. Page 4, what was the operational definition of a positive SLR test in terms of ROM? Did the symptom reproduction have to occur below 70 degrees? 45 degrees? These two thresholds are both described in the literature. The authors should clarify their definition of a positive test.

3. Figure 2 – The authors should detail which of the study’s inclusion/exclusion criteria caused ineligibility among the 70 subjects who failed to qualify for the study.

Discretionary Revisions (which the author can choose to ignore)

What next?: Reject because scientifically unsound
Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
'I declare that I have no competing interests