Reviewer's report

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

Version: 1 Date: 1 May 2007

Reviewer: Helen Frost

Reviewer's report:

General
This paper describes a feasibility study of lumbar traction for patients with acute and sub-acute low back pain. The study is presented well but the title of the paper and the interpretation of results are misleading.

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

1) The title should make it clear that the paper describes a feasibility study not imply that it evaluates the effectiveness of lumbar traction.

2) The design of the randomised controlled trial is described as single blind but in fact the patients and the care providers are not blind to treatment allocation and therefore the study is investigator blind only.

3) Four primary outcome measures are included without references.

4) There needs to be a clear explanation in the methodology of which outcome is used to calculate the sample size and what time point was measured.

5) The treatment is described well and would be easily replicated but the description of the statistical analysis needs further clarification. Primarily there is no mention of an intention to treat analysis which would be appropriate for this design. The description of the patients that were lost to follow up is confused with those that failed to complete treatment (i.e. non compliers). It appears that seven patients were excluded from the analysis when actually only three failed to return the outcome measures. The decision to include or not include patients in the final analysis should be stated in the protocol and not decided post randomisation.

6) The recruitment phase was slow and results suggest that the design of the trial is not a feasible model for ethical and financial reasons. The outcome of the study was predictable, firstly because the patients had acute and sub-acute pain that was likely to improve spontaneously over time and secondly because there was very little difference between the treatment protocols. The most notable findings of recent larger trials have shown that only small treatment effects are likely from most conservative treatments for back pain and the addition of traction to a package of care was very unlikely to demonstrate any treatment gains. The authors correctly point out that the small sample size, with only 77% follow up, resulted in an underpowered study. Interpretation of the results is misleading as the authors make a number of suggestions based on data that are clearly not statistically robust.

6) In the discussion the interpretations of the results of the study are inconsistent with the aims and design of the protocol. In the first paragraph of the discussion the authors claim that patients benefited significantly from both treatment protocols but there was no control group. The trial was designed to assess the differences between treatments not whether both treatment protocols impacted on disability or pain. It is likely that the patients simply recovered spontaneously.

7) In the conclusion the authors identify sub grouping as the most important design issue of the study although it was not stated as the main aim in the methods.

8) In the conclusion the authors state that the study demonstrated that the addition of traction to a standardised protocol did not give additional improvement. The results may suggest that traction is not effective but this study was underpowered and the conclusion should be that the trial wasn’t feasible. The
very large number of patients that would be needed to demonstrate a significant difference (clinically or statistically) between groups would make a further trial expensive and a waste of patient’s time and resources.

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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) In the results section four of the figures don’t have a number.

2) The SF-36 physical and mental component scores are baffling (range 0-350?) and do not relate to the scores in the table.

3) 1) It would be informative to present confidence intervals of the differences between groups.

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Discretionary Revisions (which the author can choose to ignore)

1) The issue of sub grouping of patients with low back pain is raised in the discussion but there are no references to support the claim that patients with ‘nerve root’ pain are a distinct sub group.

2) It would be useful to provide a definition of the meaning of a clinically significant difference or cite a reference (page 10, paragraph 1). This is a contentious issue in back pain research and needs clarifying in this context.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

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 interest