Reviewer's report

Title: The effectiveness of a specific exercise program in addition to first-line care for acute low back pain: A randomised controlled trial

Version: 1 Date: 2 September 2009

Reviewer: Julie Fritz

Reviewer's report:

The authors of this manuscript report the results of a randomized clinical trial comparing two management strategies for patients with acute low back pain in primary care. In general the study was conducted according to high methodological standards, and is reported in a clear and concise manner. The study certainly addresses an important research topic and has the potential to make an important contribution to the literature on the treatment of patients with acute LBP. There are several areas of concern, that if addressed could enhance the credibility of the manuscript.

My concerns and recommendations with the manuscript are outlined below.

Major Compulsory Revisions:

The treatment program being examined in this study should be consistently labeled as “McKenzie Therapy” or something similar that clearly indicates the treatment approach that is being examined. The term “Specific Exercise” is a broad term that could mean many different things. In addition, the group in this study received more than exercise, they received an approach consistent with McKenzie philosophy, which includes more than exercises. The clarity of the manuscript will be significantly enhanced by using a more precise and descriptive label for this group.

The results of the study for the outcome of pain found a statistically significant difference between groups, however this mean between-group difference was below the threshold the authors’ established to define a minimally important difference in pain (1 point change). It is important to recognize, however, that a minimally important difference threshold is generally approached statistically and conceptually as referring to the change that is considered important at the level of the individual patient, not at the level of mean between-group differences. The reporting of the results would be improved if the authors reported these outcomes as the proportion of patients in each group achieving at least a minimum clinically important level of change, in addition to the mean between-group differences. This approach matches the individual-patient concept of an MCID with the reporting of the results, and is recommended to improve the interpretability of clinical trials (see for example - Guyatt GH, Schunemann HJ. How can quality of life researchers make their work more useful to health workers and their patients? Qual Life Res 2007;16:1097-105).
The difference in the proportion of patients in each group attaining at least a minimally important level of change can be tested statistically, and will help the authors to interpret whether there is indeed an important difference between the groups.

It does not appear that the authors evaluated the adherence to protocol of either the physical therapists or primary care physicians. This issue should be dealt with more explicitly and acknowledged as a limitation unless some effort in this regard was in fact undertaken.

A sensitivity analysis examining the results among patients in the exercise group who were adherent to the activities prescribed by their physical therapist would be of interest.

Page 5, paragraph 1 – The contention that referral for McKenzie treatment for patients with acute LBP at the initial contact with primary care is “common clinical practice” requires justification and referencing. While those who support McKenzie methods would endorse the ability of this approach to benefit patients with acute LBP, surveys of practice patterns in various countries do not indicate that McKenzie methods are the predominant treatment approach used by physical therapists, and I am not aware of any data supporting the contention that primary care providers are particularly likely to refer patients explicitly for McKenzie-based therapy.

Page 6, paragraph 1 – please clarify how the presence of nerve root compromise or “red flags” was determined when screening subjects for eligibility. Was this left to the judgment of the primary care provider or was an explicit process for screening used?

Page 10, paragraph 3 – In the Statistical Analysis section, please clarify how missing data points were handled.

Page 11, paragraph 2 – The authors indicate that 260 consecutive patients were screened across 31 primary care providers over a 27-month period. This would equate to approximately 1 patient every 3 months per primary care provider. Unless these primary care providers had a rather atypical patient load, it would seem that many potentially eligible patients seen in primary care by these providers were simply not screened. It is understandable that the exact number of potentially eligible patients who were missed would be difficult to ascertain, but this needs to be acknowledged as a potential source of bias in the study. It may not be accurate to consider this screening of “consecutive patients”.

Figure 1 – Please add the specific criterion on which the subjects were excluded based on not meeting the inclusion criteria (n=57) or meeting the exclusion criteria (n=22). Please add the follow-up at 3 months at which recurrent was determined.

Table 2 – It’s not clear why p-values are listed separately for the 1-week and 3-week time-points separately, while the outcomes of pain, disability and function have only an overall p-value that is reported. Please be consistent with the
approach to presenting this information.

Minor Essential Revisions:

Page 4, paragraph 2 – In the first sentence, please clarify to whom “these patients” refers.

Page 4, paragraph 2 – I believe it would be more accurate to state “However, the scientific evidence to support the use of these specific exercises is still scarce, particularly for patients with acute LBP”. It seems that the issue is the value in managing patients with acute symptom onset, not necessarily who the referral source may be.

Page 9, paragraph 1 – please clarify the procedures for the daily pain rating – were subjects asked to rate their worst level of pain on each day? The average level of pain for that date?

Page 9, paragraph 3 – Please clarify the procedures used by the physical therapists to assess participant compliance with the treatment program. It appears that at each physical therapy visit the therapist asked the participant if he or she was performing their prescribed exercises and activities – was the participant asked if they completed this every day (since their last visits), or just if in general they were doing these activities? How was it determined that a participant was compliant at a particular consultation – did it require that the participant did their exercises every day?

Page 15, paragraph 1 – The contention that “it is doubtful that effects superior to those reported here could be obtained by other therapists” is of dubious validity. There is no evidence in the literature that certification by the McKenzie Institute (or other organizations) results in superior outcomes (see for example Resnik and Hart. Phys Ther 2003: 83:990-1002) It may be accurate to say that it is doubtful that other therapists would have been more likely to deliver the treatment with fidelity to McKenzie principles, but it not defensible to state that other therapists would be unlikely to obtain superior effects.

Which journal?: Not appropriate for BMC Medicine: an article whose findings are important to those with closely related interests and more suited to BMC Musculoskeletal Disorders

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

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