Reviewer’s report

Title: The effectiveness of the McKenzie method in addition to first-line care for acute low back pain: A randomized controlled trial

Version: 2 Date: 9 December 2009

Reviewer: Teresa Liu-Ambrose

Reviewer’s report:

My original comment:
In sample size justification, authors need clarify when they expected the 1 unit difference in pain score and the 1.2 unit difference in global perceived effect scale. In turn, those should be the primary outcome measures (e.g, pain at 3 weeks).

Authors Response:
We designed the study to have sufficient power to detect the specified differences and it would not matter at what time point the test was conducted because time is not a parameter in sample size estimations.

The primary outcomes were specified a priori “primary outcomes were mean pain over the first week, pain at 1 week, pain at 3 weeks and global perceived effect at 3 weeks”

My response is:
In a RCT sample size justification, you are expected to hypothesize what is your primary statistical analysis -- such that you do need to specify at what time frame you expect to see a between-group difference in your primary outcome measure. Otherwise, when you have a trial with multiple measurement sessions, multiple comparisons becomes an issue.

Otherwise, fine to accept.