Reviewer's report

Title: The ANKLE TRIAL (ANKLE TReatment after Injuries of the Ankle Ligaments): what is the benefit of external support devices in the functional treatment of acute ankle sprain? : a randomised controlled trial

Version: 2 Date: 19 July 2011

Reviewer: Carl J Lombard

Reviewer's report:

The authors have addressed the elements pertaining to the CONSORT guidelines adequately. This is an improvement. The authors provide more detail on the sample size calculation. The outline to referee 2 and the expanded text is fine if this was a protocol with a comparative hypothesis. I quote from the abstract:

"(The) Hypothesis of our study is that in the treatment of acute ankle sprains external ankle support devices will not result in better outcome, compared to a purely functional treatment strategy"

This hypothesis is fine and makes a lot of sense. As outlined in my previous review this is a hypothesis of non-inferiority - the Karlson score at the end of follow-up will be the same with a certain bound. The sample size calculations for this hypothesis is not that given in the text. The authors should review my comments in the previous review and correct this. The statistical analysis for assessing non-inferiority should also be stated.

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

Quality of written English: Needs some language corrections before being published

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

Declaration of competing interests:

'I declare that I have no competing interests'