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:** 3  **Date:** 22 September 2011

**Reviewer:** Carl J Lombard

**Reviewer's report:**

Major essential revisions:

The description of the statistical analysis is too limited given that this is a non-inferiority trial. The study will benefit by using the repeated measures nature of the Karlson score at 6, 24 and 52 weeks. An ANOVA at each time point is also not the correct inference. The hypothesis of non-inferiority has to be approached through the estimation of confidence intervals. This can be done in a single model across all three time points giving improved precision since within participant variability is accounted for. The analysis should be presented in more detail.

Note: it is not advisable to formally compare baseline values since any differences observed are due to randomisation. The baseline value of the Karlson score can be used as a co-variate in the longitudinal regression model to improved precision further. You want to have good precision since the limits of the confidence interval have to lie within the equivalence bound of 10%.

The sample size formulation is appropriate - one could give the general mean Karlson score at say on of the time points as reference for the equivalence limit. A reference to another study is made but adding this bit will make it ven better.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

'I declare that I have no competing interests'