Reviewer's report

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

Version: 1 Date: 19 May 2011

Reviewer: Carl J Lombard

Reviewer's report:

When referring to CONSORT elements it relates to the 2010 checklist from the CONSORT Group website

1. The title of the trial is confusing especially the wording "surplus of external support" Benefit of external support would be an improvement. Surely the benefit does not relate to the functional treatment but to the long term recuperation as stated in the outline on p6?

2. Objectives: why is the 2002 Cochrane review still relevant? You used results from later trials in the planning of your study. The wording of the objective follows the same vein as the title - focussing on the methodology rather than the purpose as given in the outline on p6.

3. Methods - many aspects of the CONSORT not followed or reported - even less of the CONSORT plus requirements. Protocol described very loosely and without much detail. Another research team will struggle to do the same study due to the lack of information.

4. P6 residual-free healing, prevention of chronic symptoms and functional instability are mentioned in the study outline. Which of the outcomes relate to these objectives?

5. P6 Bauerfiend to provide the used braces? Surely you are not going to use second hand or previously-owned braces :). Do patients have to pay for participating in the trial and pay to receive any parts of the treatment? If one of the study arms indicate harm what will be done?

6. Hypothesis. As stated the study team is stating a non-inferiority hypothesis with non-inferiority bound of 10%. This is fine but the problem comes in that the sample size calculation is based on a superiority hypothesis/analysis. This is a serious problem for the study and should be resolved and would require a protocol amendment to get the two to match.

The sample size calculation is done for a two group comparison when there are three groups being randomised. The sample size should surely be based on the test statistic that will be used for the primary outcome compared across the three groups.
7. Very limited description of inclusion and exclusion criteria is given. How will the diagnosis of the type and severity of sprain be done? How will this be implemented consistently accross the three sites?

8. The description of the three sites are muddled and limited. Do they serve the same population in general? Do all of them operate over 24 hours?

9. The type of randomisation used is absent (CONSORT 8b). Mechanism (CONSORT 9) Who generatios random allocation etc (CONSORT 10. Blinding (CONSORT 11a) are elemenst that are absent. Will the follow-up measurement of the outcomes be done by a blinded clinician or evaluator? If not why not? Do the sites have a minimum sample size to complete?

10. (CONSORT 5) Description of the interventions: no description of the ankle excercise scheule is given. the same goes of the tape treatment, brace treatment and purely functional treatment.

11. Outcome measure. How is the Karlson scale outcome opbtained - self completed, by interview? The same goes for the secondary outcomes.

12. (CONSORT 12a&b) The description of the statistical methods is missing. Handling of dropouts for which 10% is expected should be included in the basic description of the analysis. How will recurrent ankle injuires be analysed - who will do this determination in an unbiased way?

13. CONSORT 23, 24 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'