Reviewer's report

Title: Effects of Soft Bracing or Taping on a Lateral Ankle Sprain in a Controlled Trial: Recurrence Rates and Residual Symptoms at one year

Version: 1 Date: 15 November 2014

Reviewer: Kasper Janssen

Reviewer's report:

Thank you for your interesting and well written study.

Major Compulsory Revisions

1. In the introduction, line 76 tot 85, you could be more concise on why this study was needed. Is it only skin irritation with tape use and loss of tape stability? Or maybe the associated costs with taping are higher than with bracing? Did you expect a difference in recurrences and residual symptoms?

2. Line 78: 'The stability of the taped ankle decreases approximately 14% after 30 minutes of exercise.', while the referenced article describes: 'there was a loss of tape stability <=14% after 30 min of athletic exercise'. Therefore, please adjust to: 'The tape stability decreases approximately 14% after 30 minutes of exercise'.

3. Line 90: 'Patients aged 18 years and older and diagnosed with an ALALS caused by an inversion trauma were recruited from 20 family practices and nine physical therapy practices in the Utrecht region, in which is located in the center of the Netherlands, and from the emergency.'

   Difficult sentence to read, please change to: 'Patients aged 18 years and older and diagnosed with an ALALS caused by an inversion trauma were recruited from 20 family practices, nine physical therapy practices, and from the emergency departments of a regional hospital and a university hospital located in the central part of the Netherlands.'

4. Line 89: Participants

   Please mention if an age limit was followed for inclusion.

5. Line 109: Please describe what 'independent' means. Does it mean for example: 'blinded for the severity of the inclusion injury'?

6. Line 111: Treatment

   Please describe if a pain medication protocol was used at initial treatment.

7. Line 126: Control group

   I am surprised that skin problems were not registered in your study, as you mention this to be an important complication of tape use. Please describe why this side effect was not reported in your study in the discussion.
8. Line 146: 'A recurrence of ALALS was defined as a new inversion trauma of the same ankle,...', does this mean you did not use a time-loss definition of ankle sprain recurrence? Please describe exactly how this question was formulated in your questionnaire.

9. Line 162: 'Being able to stand on one leg for 15 seconds was classified as having successfully accomplished a one-leg stance test.' Please describe the cut-off point for a successful test in more detail.

10. Line 166: 'Pain during walking, running, pivoting, and jumping was reported by the patient. Patients were classified as having pain (Yes/No) when they reported pain during at least one of these activities.' I assume you mean pain in the ankle joint. Please describe.

11. Line 170: 'In addition, data on the compliance of wearing the soft brace or tape, and the use of medication and other therapy were collected during the five-week online questionnaire.' This means these data were self-reported, please mention this when you refer to these data.

12. Line 174: 'The incidences of the primary outcome (ALALS recurrence) were expected to be similar in both treatment groups.' For readability please change to: 'The incidences of ALALS recurrences were expected to be similar in both treatment groups.'

13. Line 191: RESULTS

In Figure 2 you mention Lost to follow-up in the brace group: 'Preferred brace over tape' I assume this should be changed to: 'Preferred tape over brace use.' Please change if my assumption is right., otherwise delete.

You mention an intention-to-treat analysis, but in figure 2 you show that participants that were lost to follow-up were not included in the analysis. Therefore you applied an 'efficacy subset analysis'. Although the numbers lost to follow-up are low, this sort of analysis might introduce some bias. Please report the use of 'efficacy subset analysis'.

14. Line 156 'The dynamic anterior ankle test was used to measure ligament stability.' In a recent study (Clinical evaluation of a dynamic test for lateral ankle ligament laxity by J. S. de Vries, 2009) this test has been shown to have a low reliability in effectively testing lateral ankle ligament laxity in a clinical setting. Please describe this in the discussion.

15. Line 245 You discuss the relationship of mechanical ankle instability with functional instability. A recent study by Hiller et proposes a new model which describes this relationship. The proposed new model of chronic ankle instability is supported by data from previous studies and their own study. More subgroups are identified than in previous models, with perceived instability as a common link. Please consider to discuss your findings with respect to this new model.

16. Line 271 'A re-injury was not assessed by a medical professional, so no detailed information about the severity of these new injuries was available.', while in the Methods section you describe: 'Ankle fractures or overload of the affected
ankle were not regarded as recurrences of ALALS. This implies that someone assessed the re-injury on several criteria. Please describe the criteria, and the person that interpreted them, in the methods section. Please also describe or discuss if this person was blinded for the intervention group.

17. Line 280 ‘We do not expect that this has influenced our results.’ Please explain why not.

18. Line 293 ‘Additional research on the treatment of ALALS needs to be conducted, focusing on effectiveness, cost-effectiveness, and the patient’s preference.’ This advise is not supported by your research. Please add a statement why you provide this advice, or delete the advice.

19. Line 300 ‘with the possible exception of the anterior drawing sign test.’ This added information does not seem appropriate in your conclusion, as you question the relevance of this finding in the discussion. Consider deleting this sentence or provide more support for making this statement.

20. Line 301 ‘These findings should be confirmed in larger randomized trials.’ Do you expect that a larger RCT will find different results? And should this trial focus on primary treatment or secondary treatment of ankle sprains? Please be more concise in your advice.

21. Line 442 Table 1. Please group baseline characteristics for readability of the table if other than N, for example years, days, etc.

Minor Essential Revisions

1. Line 116: 'Only in case of very severe ankle swelling was the ICE treatment continued and the allocated intervention was postponed for a few additional days (average 3-4, with a maximum of six days).’ For readability please change to: 'Only in case of very severe ankle swelling the ICE treatment was continued and the allocated intervention was postponed for a few additional days (average 3-4, with a maximum of six days).

2. Line 198: 'A total of 57 patients (36%) of which 30 in the brace and 27 in the tape group, visited a physical or manual therapist during the treatment period after the initial trauma.' Do you know how many treatment sessions were followed in each group? If so, please describe as this might influence ankle function.

3. Line 214: 'Seventeen patients underwent no physical examination after one year of follow-up....'For readability please change to: 'Seventeen patients were lost to follow-up and therefore did not have a physical examination after one year.'

I wish you success in adjusting this study for publication!

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

**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