

**A randomised placebo controlled trial of the management of non-specific low back pain using the Nubax® vertebral distraction device.**

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**ABSTRACT**

**Objective:** To determine whether the use of the Nubax® home traction device with a multimodal physiotherapy program including core stability exercises and low back massage is effective in managing chronic low back pain, and if benefits can be maintained with self management.

**Methods:** Randomised, single blind, placebo-controlled trial; 53 community volunteers with chronic low back pain participated and 41 completed the trial. Physiotherapy treatment included low back soft tissue massage and three core stability exercises applied by one physiotherapist in private practice for 6 weeks. This was done in conjunction with the use of a combination of treatment unit, the Nubax®, and a placebo or sham unit, over 3 – 6 weeks with a cross-over period at 3 weeks for two groups and a full 6 week treatment block for one group. Primary outcome measures were quality of life measured by the Roland Morris Disability Questionnaire (RDQ) and a modified version of the Western Ontario and McMasters Universities Arthritis Index (WOMAC), which assessed the domains of pain, stiffness and physical function.

**Results:** Using an intention to treat analysis, treatment and placebo/sham groups showed differing results at 3 weeks with significant changes in results between groups post 6 weeks. At 3 weeks, WOMAC total score and quality of life had improved for those subjects using the Nubax® unit compared with those using the placebo/sham device. At 6 weeks those using the Nubax® unit continued to improve whilst those who crossed over to the placebo/sham unit deteriorated and those commencing on the treatment unit from the placebo made greater improvements.

**Conclusions:** The use of the Nubax® home traction unit in this study was more effective than basic physiotherapy treatment alone at improving patients' quality of life and physical function, while reducing pain and stiffness after 3 weeks of treatment.

## **FIGURE CAPTIONS**

- Figure 1. Patient set-up and operation of the Nubax®.
- Figure 2. The mean and 95% confidence limits of the Modified WOMAC total change scores for the sham and treatment intervention groups for weeks 0-3.
- Figure 3. The mean and 95% confidence limits of the Modified WOMAC physical function change scores for the sham and treatment intervention groups for weeks 0-3.
- Figure 4. The change scores for the modified WOMAC total score for the three groups for the performance for the first block of treatment (week 0 to 3) and for the whole treatment (week 0 to 6 filled triangles). Group A = treatment to sham crossover; Group B = 6 week treatment; Group C = sham to treatment crossover.

Fig 1.



Fig 2.

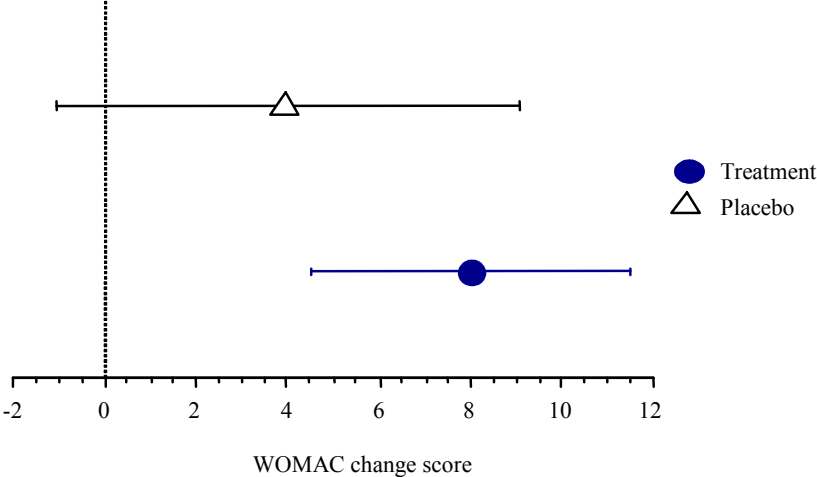


Fig 3.

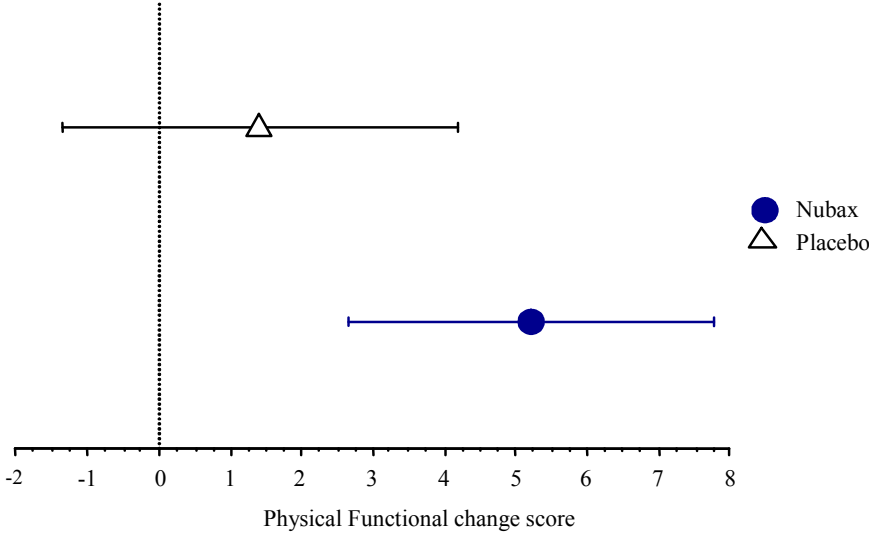


Fig 4.

