



The effectiveness of ENAR[®] for the treatment of chronic neck pain in Australian adults: a preliminary single-blind, randomised controlled trial.

and the National Institutes of Health

1: Chiropr Osteopat. 2007 Jul 9;15:9. (See also: http://www.chiroandosteo.com/content/15/1/9)

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BACKGROUND: Current evidence on electrotherapies for the management of chronic neck pain is either lacking or conflicting. New therapeutic devices being introduced to the market should be investigated for their effectiveness and efficacy. The ENAR (Electro Neuro Adaptive Regulator) therapy device combines Western biofeedback with Eastern energy medicine.

METHODS: A small, preliminary randomised and controlled single-blinded trial was conducted on 24 participants (ten males, 14 females) between the ages of 18 to 50 years (median age of 40.5) Consent was obtained and participants were randomly allocated to one of three groups--ENAR, Transcutaneous Electrical Nerve Stimulation (TENS), or control therapy--to test the hypothesis that ENAR therapy would result in superior pain reduction/disability and improvements in neck function compared with TENS or control intervention. The treatment regimen included twelve 15-minute treatment sessions over a six week period, followed by two assessment periods. Visual Analogue Scale (VAS) pain scores, Neck Disability Index (NDI) scores, Patient Specific Functional Scale (PSFS) scores and Short Form 36v1 (SF-36) quality of life scores reported by participants were collected at each of the assessments points throughout the trial (0, 6, 12, 18 and 24 weeks).

RESULTS: Eligible participants (n = 30) were recruited and attended clinic visits for 6 months from the time of randomisation. Final trial sample (n = 24) comprised 9 within the ENAR group, 7 within the TENS group and 8 within the control group. With an overall study power of 0.92, the ENAR group showed a decrease in mean pain score from measurement at time zero (5.0 +/- 0.79 95%CI) to the first follow-up measurement at six weeks (1.4 +/- 0.83 95%CI). Improvement was maintained until week 24 (1.75 +/- 0.9 95%CI). The TENS and control groups showed consistent pain levels throughout the trial (3.4 +/- 0.96 95%CI and 4.1 +/-0.9 95%CI respectively). Wald analysis for pain intensity was significant for the ENAR group (p = 0.01). Six month NDI scores showed the disability level of the ENAR group (11.3 +/- 4.5 95%CI) was approximately half that of either the TENS (22.9 +/- 4.8 95%CI) or the control (29.4 +/- 4.5 95%CI) groups. NDI analysis using the Wald method, indicated significant reductions in disability only for the ENAR group (p = 0.022). PSFS results also demonstrated significantly better performance of ENAR (p = 0.001) compared to both alternative interventions. Differential means analysis of the SF-36 results favoured ENAR for all of the subscales. Six of the initial 30 participants discontinued the trial protocol.

CONCLUSION: ENAR therapy participants reported a significant reduction in the intensity of neck pain (VAS) and disability (NDI), as well as a significant increased function (PSFS) and overall quality of life (SF-36) than TENS or control intervention participants. Due to the modest sample size and restricted cohort characteristics, future larger and more comprehensive trials are required to better evaluate the potential efficacy of the ENAR device in a more widely distributed sample population. TRIAL REGISTRATION: This study has been registered with the Australian Clinical Trials Registry (ACTR): ACTRN012606000438550.

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