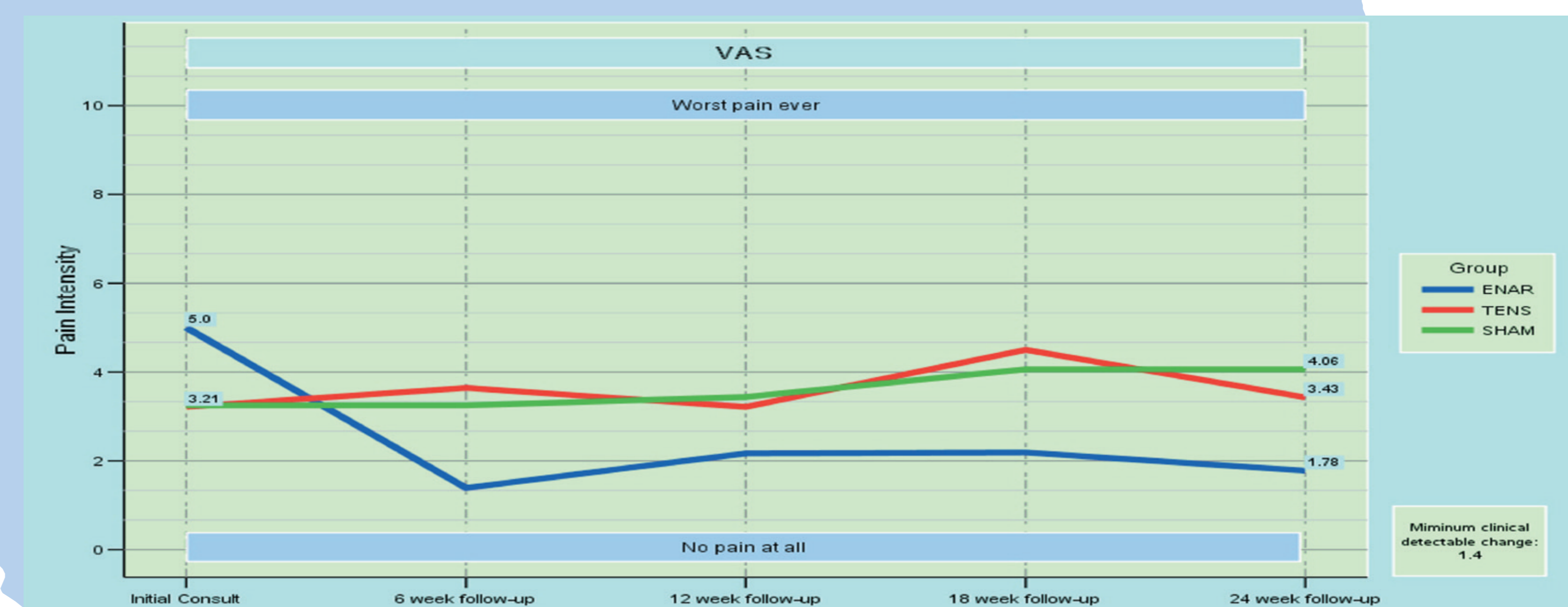
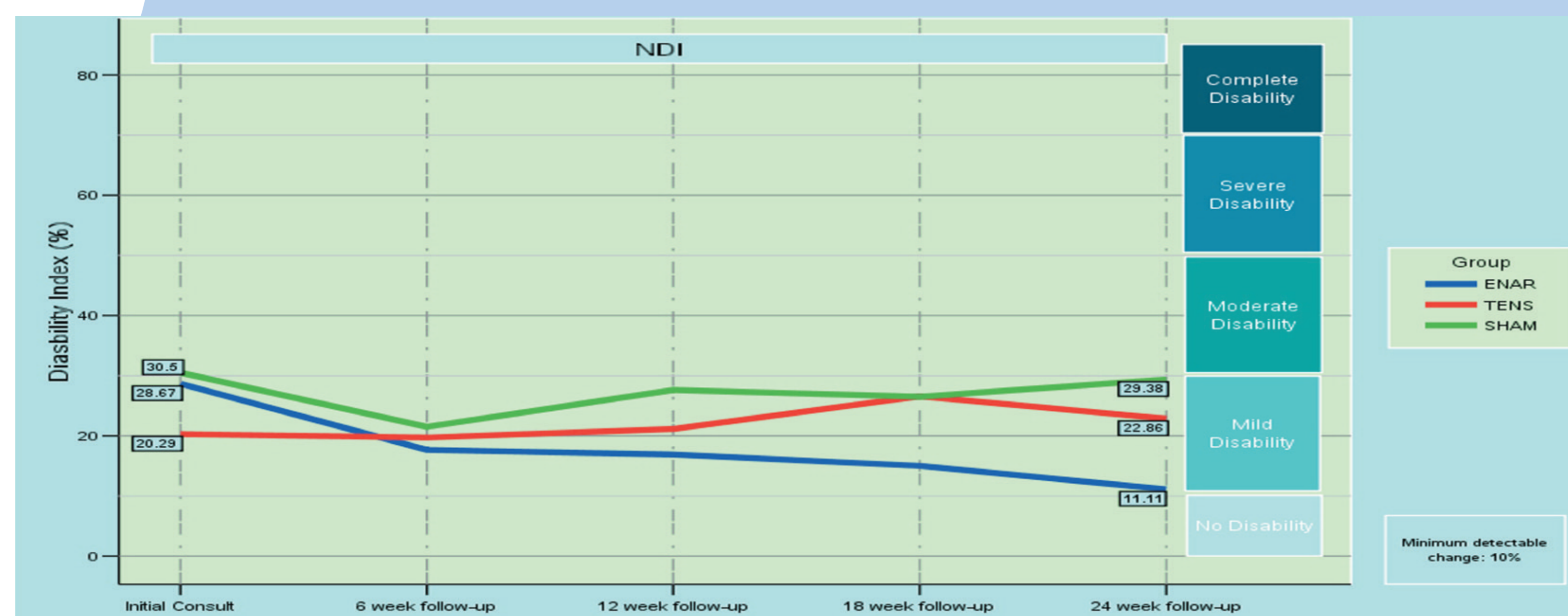
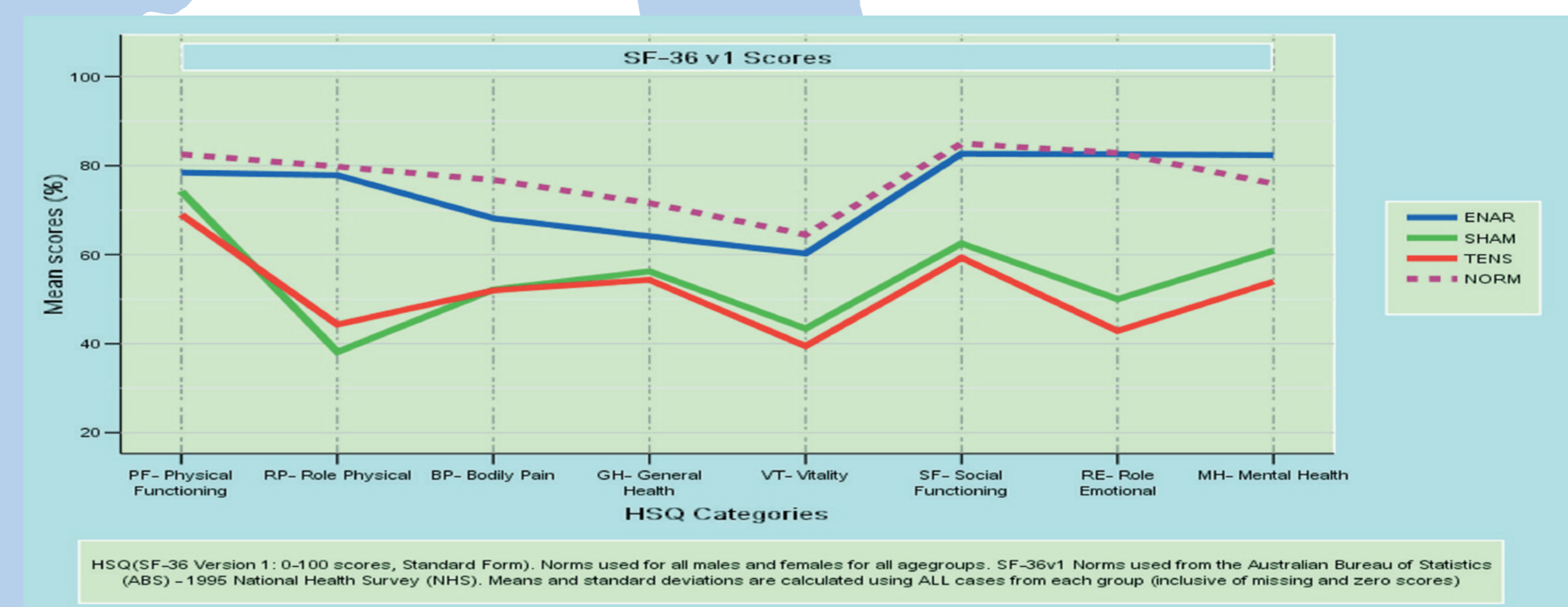
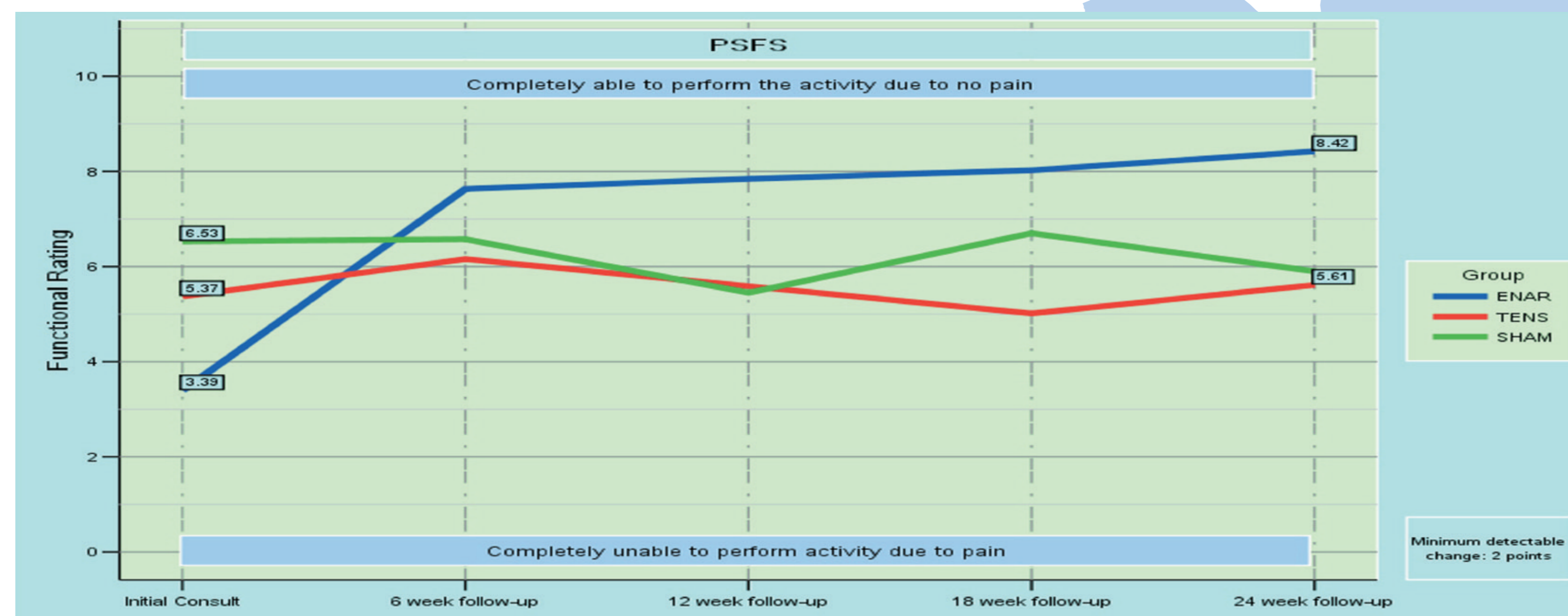


# A Phase 2 Pilot Study on the Effectiveness of ENAR Therapy on Chronic Neck Pain - 6 month Follow-Up

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**Introduction:** The aim of the study was to study the longer-term effects of ENAR therapy on a randomly selected group (n=24) of patients suffering from non-complicated chronic neck pain. Following a 12 visit treatment protocol (6 weeks) of either ENAR, TENS or Placebo treatment, the cohort was followed for a further period of 18 weeks in order to assess the effects of each therapy using a variety of subjective and objective outcome measures.

**Methods:** Following a 12 visit treatment protocol lasting 6 weeks (Phase 1) subjects were examined 6 weekly for a total period of 6 months (1,6,12,18 and 24 weeks). At each examination period subjects were instructed to complete Visual Analogue Scale (VAS), Neck Disability Index (NDI), Patient Specific Functional Scale (PSFS) and Short Form 36 (SF-36) outcome measures in order to assess the effectiveness of the respective therapies for non-complicated Chronic Neck Pain (NCCNP).



**Results:** The ENAR therapy was successful in reducing the intensity of neck pain (VAS) from  $5.0 \pm 0.77$  (95%CI) to  $1.75 \pm 0.90$  over the 6 months while participants receiving the TENS & Sham therapies had showed no change or an increase in pain ( $3.24 \pm 0.83$  to  $3.43 \pm 0.99$  and  $2.86 \pm 0.83$  to  $3.79 \pm 0.99$ , respectively). Similar trends were observed in Neck Disability Indices (NDI) with ENAR recipients having reductions from  $30.75 \pm 3.01$  (95% CI) to  $11.25 \pm 4.59$  while the TENS and SHAM treatment recipients showed no change ( $20.27 \pm 3.22$  to  $22.86 \pm 4.91$  and  $29.43 \pm 3.22$  to  $28.43 \pm 4.91$ , respectively). Improvements in Patient Specific Functional

Scales (PSFS) were also noticed among ENAR participants with reported improvements over 6 months of  $3.57 \pm 0.69$  to  $8.48 \pm 0.94$  (95% CI). Patients receiving the TENS and SHAM treatments again showed no change in overall neck function ( $5.37 \pm 0.75$  to  $5.61 \pm 1.00$  and  $6.53 \pm 0.75$  to  $5.96 \pm 1.00$ , respectively). Qualitative analysis of Sf-36 results using the COES<sup>®</sup> clinical software package, and comparing the cohort to the 1995 ABS National Health Survey, found that patients undergoing the ENAR therapy had results more closely following the trends of their 1995 nationally matched counterparts compared with patients receiving either the TENS or SHAM treatments.

**Conclusion:** Despite the low power of the study groups (VAS (0.156), NDI (0.255) PFSF (0.211)), the authors were able to successfully highlight clinically significant trends in reducing the signs and symptoms associated with non complicated neck pain in patients receiving ENAR therapy compared to both TENS and SHAM therapies.

Further studies are required, using a much larger cohort size, to increase the power of the study and thereby confirm statistically the clinically significant trends in VAS, NDI, PSFS and SF-36 outcomes found in this pilot study.

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