

Weiner DK, Perera S, et al. Efficacy of Percutaneous Electrical Nerve Stimulation [PENS] and Therapeutic Exercise for Older Adults with Chronic Low Back Pain: A Randomized Controlled Trial. Pain 2008;140(2): 344-357.

Design: Randomized clinical trial

Population/sample size/setting:

- 200 older adults (86 men, 116 women, mean age 74) treated for chronic low back pain at the University of Pittsburgh
- Inclusion criteria were age over 65, English speaking, with low back pain every day or nearly every day, of moderate intensity, for at least 3 months
- Exclusion criteria were red flags (fever, weight loss, sudden recent change in pain intensity or character, recent trauma), prominent radicular pain, back surgery, known spinal pathology other than degenerative disease, pain outside the back more severe than the low back pain, medical instability, contraindications to exercise (arrhythmias, unstable angina, etc), neurological or psychiatric disorder that could interfere with pain reporting

Main outcome measures:

- Randomized with stratified blocked randomization to one of four groups: (1) PENS, (2) control PENS, (3) PENS plus general conditioning and aerobic exercise (GCAE), and (4) control PENS plus GCAE
- PENS and control PENS were administered by an acupuncturist who was masked as to whether participants were randomized to receive GCAE; both were administered twice per week for six weeks
- At each PENS session, ten 32-gauge 40 mm acupuncture needles were placed just below the skin to a depth of about 15 mm at levels corresponding to T12, L3, L5, and S2, and the motor point for the piriformis muscle; a specific pattern of electrical stimulation was applied for 30 minutes at a frequency determined by response to the previous session (the T12 needle was stimulated for 5 minutes at a frequency of 100 Hz)
- Control PENS used the same needle placement as PENS, with 30 minute sessions, but only the T12 needle was electrically stimulated, and only for 5 minutes, also at the frequency of 100 Hz that the PENS group received
- GCAE was enacted under the supervision of a physical therapist, with general conditioning (strength and flexibility) and aerobic exercises (treadmill or stationary bicycle); each on site session lasted 60 minutes
- CGAE on site sessions were administered twice per week for six weeks; in addition, a home exercise program, targeting the lower extremity and low back muscles, was to be done three times per week for six weeks
- Primary outcomes were pain intensity on the McGill Pain Questionnaire (MPQ) and self-reported disability on the Roland and Morris Questionnaire (RMQ), which is scaled from 0 to 24 (high score=more disability)
- Secondary outcomes included performance-based physical function (repeated rising from a chair, gait speed over 25 feet, timed stair climbing) plus self-

- reported scales for psychosocial function (depression, fear-avoidance beliefs, catastrophizing), sleep, and health-related quality of life (SF36)
- Overall dropout rate was 8%
 - Improvements were observed in all groups over the course of the study
 - Numerous comparisons were made of the changes in pain, function, and other scores over time, but the salient ones are few
 - o Most outcome changes did not depend on which treatment group the participant was assigned to
 - o GCAE did not significantly enhance pain reduction or functional improvement, but GCAE did reduce fear avoidance beliefs
 - RMQ at baseline was about 10 in all groups, and the decrease in RMQ over the course of 6 months was about 2.5 points (generally regarded as clinically significant)
 - One person dropped out because of increased back pain; no adverse effects were reported for any of the interventions
 - Treatment credibility was assessed at the end of session 2 and the end of session 8; there were no significant between-group differences in credibility, but increased credibility was associated with increased improvement scores

Authors' conclusions:

- Six weeks of twice weekly PENS, whether electrically stimulated for 30 minutes or for only 5 minutes, significantly reduces pain and improves function without significant side effects
- The magnitude of pain reduction and functional improvement is similar to that of other multidisciplinary treatments for chronic low back pain
- The comparable improvements in the PENS and the control PENS groups are in contrast to the differences which were observed when PENS was compared to the placement of the acupuncture needles with no electrical stimulation
 - o This may be related to treatment expectancy, as suggested by the association between credibility and improvement
 - o It may be associated with an analgesic effect of the brief electrical stimulation delivered by the control PENS procedure
- The participants in this study were comparatively frail, and the effects of treatment may be different in more robust adults
- Lumbar spinal stenosis is a common condition in older adults; it was an exclusionary criterion in this study, and the effects of the study interventions may be different in that setting

Comments:

- Control PENS was set up as a sham procedure (and in Table 4 is called "sham" PENS); the authors appear to be ambivalent about whether the five minute electrical stimulation at the single T12 needle constituted an active treatment
- An effort was made to compensate for an imperfect placebo group by creating a structurally equivalent placebo: one with the same frequency and duration of application as the active intervention

- The interpretation of the effect of PENS is difficult, since there appears to be no clear distinction between the effect of a short electrical stimulation and the effect of treatment expectancy on the outcome
- There was no control group which had only GCAE; all groups had either PENS or control PENS
- Similarly, there was not a control group which had usual treatment or waiting list referral
- Several interpretations of the results are compatible with the data; the interpretation that PENS is effective is one of them, but not the only one
- The insertion of acupuncture needles had no adverse effects in this study group; the authors interpret this as a safety advantage over NSAID and other drug treatments, which may have side effects
 - o No participant was taking opioids at baseline
 - o There is insufficient information about medication use to support the hypothesis that PENS reduces the use of prescription medication
 - o Therefore, the potential for PENS to prevent side effects from prescription medication remains a matter of speculation

Assessment: Inadequate for evidence that PENS effectively reduces low back pain (the nature of the comparison intervention is too ambiguous)