**Table E34. Data abstraction of randomized controlled trials of PENS**

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| **Author, Year** | **Country**  **Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** |
| Hamza, 1999 | USA  Single center | >18 years of age, low back pain with  radiologically confirmed degenerative lumbar disc disease, pain level stable for ≥3 months  Exclude: Radicular component, history  of drug or alcohol abuse, previous acupuncture, recent change in analgesic medications or use of opioids | Number randomized:  75  Analyzed: Unclear  Attrition: Not reported | A: PENS: 10 32-gauge needles placed into low back pain to  depth of 2-4 cm in a dermatomal (or sclerotomal) distribution of pain for 60 minutes; connected to bipolar leads at alternating frequency of 15 and 30 Hz for 45 minutes (maximum amplitude  25 mA using unipolar square-wave pattern and pulse width of  0.5 ms)  B: PENS: Stimulation for 30 minutes C: PENS: Stimulation for 15 minutes D: PENS: Stimulation for 0 minutes  Crossover design, each intervention administered 3 times a week for 2 weeks, with 1 week between treatments (total 11 weeks) |
| Pérez-Palomares,  2010 | Spain  Single center | >18 years of age, non-radicular low  back pain ≥4 months or shorter duration if unresponsive to therapy Exclude: Fibromyalgia syndrome, structural lesions in the lumbar column, concomitant non-pharmacological treatments, co-morbid medical conditions or circumstances that might have impacted results | Number randomized:  122  Analyzed: 112  Attrition: 8.9% (10/122) | A: PENS: Eight 0.3 x 25 mm needles placed into low back pain  to depth of 2-2.5 cm 8 in a dermatomal distribution, 0.3 ms impulse duration, for 30 minutes (n not reported)  B: Dry needling: 0.30 x 40 mm needles inserted into trigger points using fast-in and fast-out Hong's technique, followed by spray and stretch technique (n not reported)  3 sessions weekly for total of 9 sessions over 3 weeks |
| Weiner, 2008 | USA Single center | ≥65 years of age, ≥moderate intensity low back pain for ≥3 months Exclude: Red flags, prominent radicular pain, prior back surgery, known spinal pathology other than degenerative disease, pain outside back greater than back pain, conditions that make PENS unsafe, absolute contraindications to exercise, medical instability, medical instability, neurological or psychiatric disorder that could interfere with pain reporting | Number randomized: 200 Analyzed: 184 Attrition: 8.0% (16/200) | A: PENS: Ten 32 gauge 40 mm needles placed at 15 mm depth placed bilaterally at levels corresponding to T12, L3, L5, and S2, and the motor point for the piriformis muscle, for 30 minutes, frequency based on algorithm; also two needles placed at T12 level with transient high frequency stimulation (control PENS procedure) (n=47)  B: PENS + exercise: Supervised strength, flexibility, and aerobic exercise, sessions 60 minutes, plus home exercise (flexibility and graded walking) three times a week for 6 weeks (n=45)  C: Control PENS + exercise (n=44)  D: Control PENS: Needles placed as for PENS, but stimulation (transient high frequency stimulation) only applied to needles at T12 level (n=48)     2 sessions weekly for total of 12 sessions over 6 weeks |

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| **Author, Year** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** | **Duration of Followup** |
| Hamza, 1999 | Mean age: 47 years (overall)  Female: Not reported  Race: Not reported  Baseline pain (mean, 0-10 VAS): 6.3 vs. 6.4 vs. 6.8 vs.  6.2 Baseline function: Not reported  Prior surgery: 42% (overall) | All chronic (≥3 months), mean duration 38  months | 2 weeks (at end of each treatment  period) |
| Pérez-Palomares,  2010 | Mean age: Not reported, 34% vs. 50% <40 years of age  Female: 81% vs. 67% Race: Not reported  Baseline pain (mean, 0-10 VAS): 6.27 vs. 6.04  Baseline function: Not reported | Acute to chronic; 84% vs. 74% <3 months | 3 weeks (at end of therapy) |
| Weiner, 2008 | Mean age (years): 74 vs. 74 vs. 73 vs. 74 Female: 58% vs. 56% vs. 60% Vs. 54% White race: 86% vs. 90% vs. 88% Vs. 94% Baseline pain (0-10): 2.5 vs. 2.4 vs. 2.4 vs. 2.3 Baseline RDQ: 10.5 vs. 10.2 vs. 11.0 vs. 10.5 | Chronic; mean duration 10.0 vs. 9.0 vs. 5.0 vs. 7.0 years | 6 months (18 weeks after end of therapy) |

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| **Author, Year** | **Results**  **(list results for acute, subacute, and chronic separately)** | **Adverse Events Including Withdrawals** | **Funding**  **Source** | **Quality Rating** |
| Hamza, 1999 | A vs. B vs. C vs. D  Pain (mean, 0-10 VAS): 1.5 vs. 1.6 vs. 2.0 vs. 5.4 at 2 weeks  Pain (percent improvement from baseline, 0-10 VAS): 40% vs. 46% vs. 22% vs. 10% (p<0.01 for A or B vs. D and p<0.05 for C vs. D)  SF-36 Physical component summary (mean improvement, 0-100): +7.1 vs. +7.4 vs.  +5.4 vs. not reported (p<0.001 for A or B vs. D and p<0.01 for C vs. D)  SF-36 Mental component summary (mean improvement, 0-100): +2.9 vs. +3.1 vs.  +2.1 vs. not reported (p<0.001 for A or B vs. D and p<0.01 for C vs. D)  Physical activity (percent improvement from baseline, 0-10 VAS): 50% vs. 53% vs.  28% vs. 8% (p<0.01 for A or B vs. D, p<0.05 for C vs. D)  Sleep quality (percent improvement from baseline, 0-10 VAS): 40% vs. 44% vs. 25%  vs. 5% (p<0.01 for A or B vs. D, p<0.05 for C vs. D)  Use of nonopioid analgesics (percent decreased in pills per day): 35% vs. 38% vs.  21% vs. 8% (p<0.01 for A or B vs. D, p<0.05 for C vs. D) | Not reported | Forest Park  Institute and Egyptian Cultural and Educational Bureau | Poor |
| Pérez-Palomares,  2010 | A vs. B  Pain (mean difference from baseline, 0-10 VAS): 2.38 vs. 2.35 (p=0.94)  >40% improvement in pain: 54% (28/52) vs. 46% (24/52), RR 1.17 (95% CI 0.79 to  1.72)  Sleep quality (mean difference from baseline, 0-10 VAS): 1.72 vs. 1.85 (p=0.68) ODI Personal care (median difference from baseline, 0-1): 0.38 vs. 0.34 (p=0.94) ODI Lifting weight: 0.59 vs. 0.06 (p=0.03)  ODI Walking: 0.17 vs. 0.15 (p=0.86) ODI Sitting: 0.21 vs. 0.33 (p=0.51) ODI Standing: 0.25 vs. 0.41 (p=0.26) ODI Social life: 0.72 vs. 0.72 (p=0.18) | Not reported | Not reported | Poor |
| Weiner, 2008 | A vs. B vs. C vs. D (mean change from baseline) McGill Pain Questionnaire (0 to 78 scale): -2.9 vs. -4.1 vs. -3.1 vs. -2.3 at 6 w, -3.4 vs. -3.8 vs. -3.1 vs. -3.3 at 6 months  RDQ (0 to 24): -2.6 vs. -2.6 vs. -3.0 vs. -2.7 at 6 w, -2.1 vs. -2.1 vs. -2.8 vs. -3.0 at 6 m Average pain last week (0 to 10): -0.7 vs. -0.7 vs. -0.6 vs. -0.6 at 6 w, -0.5 vs. -0.6 vs. -0.5 vs. -0.6 at 6 m Geriatric Depression Scale: 0.3 vs. -0.4 vs. -0.3 vs. -0.2 at 6 w, 0.5 vs. -0.1 vs. -0.1 vs. -0.4 at 6 m SF-36 composite mental health (0 to 100): 1.5 vs. -0.3 vs. 2.8 vs. -0.1 at 6 w, -1.8 vs. -0.2 vs. 1.5 vs. 1.2 at 6 m SF-36 composite physical health: -1.1 vs. 3.9 vs. 6.9 vs. 5.9 at 6 w, -0.4 vs. 0.1 vs. -0.6 vs. -0.4 at 6 m Pittsburgh sleep score: -0.2 vs. 0.002 vs. -0.7 vs. 0.0 at 6 w, -0.4 vs. 0.1 vs. -0.6 vs. -0.4 at 6 m Moderate or major global improvement: 58% vs. 58% vs. 66% vs. 56% at 6 w, 40% vs. 55% vs. 50% vs. 44% at 6 m  p>0.05 for all outcomes at both time points for A vs. D, B vs. C, B vs. A, and C vs. D | "No significant intervention-associated adverse events," one participant dropped out because of increased back pain | National Institutes of Health (NCCAM and NIA) | Fair |

**Please see Appendix C. Included Studies for full study references.**