Efficacy of Percutaneous Electrical Nerve Stimulation for the Treatment of Chronic Low Back Pain in Older Adults

Debra K. Weiner, MD,[*†‡] Thomas E. Rudy, PhD,[†‡§] Ronald M. Glick, MD,[#] J. Robert Boston, PhD,[‖] Susan J. Lieber, MS, OTR/L,[‡] Lisa A. Morrow, PhD,[†] and Stephen Taylor, DO[¶]*

OBJECTIVES: To determine the efficacy of a complementary analgesic modality, percutaneous electrical nerve stimulation (PENS), for the treatment of chronic low back pain (CLBP) in community-dwelling older adults.

DESIGN: Randomized, controlled clinical trial.

SETTING: University of Pittsburgh Pain Evaluation and Treatment Institute.

PARTICIPANTS: Thirty-four English speaking, community-dwelling adults aged 65 and older with CLBP of at least moderate intensity experienced every day or almost every day.

INTERVENTION: Subjects were randomized to receive twice-weekly PENS and physical therapy (PT) or sham PENS and physical therapy for 6 weeks.

MEASUREMENTS: At baseline, immediately after the 6-week intervention period, and 3 months later, the primary outcome measures pain intensity and pain-related disability were assessed. The secondary outcome measures physical performance (timed chair rise, functional reach, gait speed, static and isoinertial lifting), psychosocial factors (mood, sleep, and life control), and cognitive function (measures of attention, concentration, and mental flexibility) were also collected.

RESULTS: Subjects randomized to PENS plus PT displayed significant reductions in pain intensity measures from pre- to posttreatment ($P < .001$), but the sham PENS plus PT group did not ($P = .94$). These pain reduction effects were maintained at 3-month follow-up. Similarly, significant reductions in pain-related disability were observed at posttreatment ($P = .002$) for the PENS plus PT group and were maintained at follow-up, but the sham PENS plus PT group did not show reductions in pain-related disability ($P = .81$). Of the secondary outcome measures, psychosocial function, timed chair rise, and isoinertial lifting endurance also improved significantly at posttreatment for the PENS plus PT group, and their improvement was sustained at 3-month follow-up, but the sham PENS plus PT did not display significant changes on these measures after treatment.

CONCLUSION: This preliminary study suggests that PENS may be a promising treatment modality for community-dwelling older adults with CLBP, as demonstrated by reduction in pain intensity and self-reported disability, and improvement in mood, life control, and physical performance. Larger studies with longer duration of follow-up are needed to validate these findings and support the use of PENS in clinical practice. **J Am Geriatr Soc 51:599–608, 2003.**

Key words: low back pain; aged; PENS; treatment outcomes

Twenty percent of community-dwelling older adults may suffer from chronic low back pain (CLBP),[1] leading to functional, emotional, and cognitive impairment; poor quality of life; and greater healthcare costs because of increased healthcare use in patients with unrelieved pain.[2,3] Although the mainstay of treatment for these individuals consists of analgesics and physical therapy (PT), patients with unrelieved symptoms have limited therapeutic alternatives. Opioid analgesics are an appropriate part of the treatment armamentarium for patients with refractory symptoms, but their associated morbidity in older adults is often limiting.[4–6] The purpose of this investigation was to explore the utility of an alternative nonpharmacological treatment modality for older adults with chronic mechanical low back pain, namely percutaneous electrical nerve stimulation (PENS), also known as percutaneous neuromodulation therapy.[7]

Because of the limitations of traditional medicine in treating chronically painful musculoskeletal disorders, many chronic pain sufferers seek complementary and alternative treatment.[8] Pain management practitioners com-

From the *Department of Medicine, Division of Geriatric Medicine, †Department of Psychiatry, ‡Department of Anesthesiology, §Department of Biostatistics, ‖Department of Electrical Engineering, and #Department of Family Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania; and ¶Department of Manipulative Medicine, University of North Texas Health Science Center at Fort Worth, Fort Worth, Texas.

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Address correspondence to to Debra K. Weiner, MD, 5750 Center Avenue; Suite 400, Pittsburgh, PA 15206. E-mail: dweiner@pitt.edu

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monly use these modalities[9] despite the fact that most have not been subjected to rigorous scientific investigation.[10,11] Acupuncture is among the most commonly used complementary medicine techniques, especially for the treatment of musculoskeletal pain.[9] Traditional acupuncture is thought to achieve its therapeutic effect by activating the flow of energy or *chi* along channels called meridians. A recent well-designed study demonstrated that traditional Chinese acupuncture is ineffective for the treatment of CLBP.[12]

Another form of pain treatment is PENS, which combines systematically placed acupuncture needles with the delivery of electrical current. In contrast to traditional Chinese acupuncture, the theoretical underpinnings of PENS lie in neuroanatomy and neurophysiology. With this technique, the needles are superficially placed along dermatomes, myotomes, and sclerotomes to activate peripheral nerves,[13] and electrical stimulation at various frequencies is used to stimulate the release of endogenous opioids.[14] The delivery of electricity rather than the precise placement of needles at acupuncture points is believed to be PENS' key therapeutic element. PENS has undergone preliminary investigation for a variety of conditions, including migraine headaches, sciatica, peripheral neuropathy, and pain associated with metastatic bone disease.[15–19] The results of one recent study suggested that PENS may be effective for the treatment of low back pain in young and middle-aged adults.[13] PENS was chosen to be studied because of its potential for broad application. Given the prevalence of dementia in community-dwelling older adults,[20] complementary pain modalities that require the use of high-level cognitive skills (e.g., biofeedback, hypnosis, relaxation) may be inapplicable to a substantial number of older chronic pain sufferers.

Although PENS may be a powerful analgesic modality for ameliorating CLBP, its application without a physical conditioning program targeted toward functional restoration would likely be suboptimal because patients with CLBP become deconditioned as a result of chronic pain-associated inactivity.[21–23] Studies in younger adults with low back pain have underscored the need to use exercise protocols and other restorative rehabilitation procedures to optimize physical performance and minimize disability.[24–27] Although the effects of exercise on older adults with CLBP have not been specifically examined, comparable benefits of aerobic exercise have been demonstrated in sedentary older adults and sedentary younger individuals.[28] Therefore, it is believed that PENS should be regarded as an analgesic modality with which to facilitate such an exercise program in older adults with CLBP.

The overall aim of this study was, using a controlled experimental design, to compare the efficacy of PENS plus PT with that of sham PENS plus PT to treat CLBP in people aged 65 and older. The primary aim of this study was to test the following hypotheses: (1) community-dwelling older adults with CLBP treated with 6 weeks of PENS plus PT will demonstrate greater reductions in pain intensity than those who receive sham PENS plus PT, and (2) subjects who received PENS plus PT will display greater reduction in self-reported disability than those treated with sham PENS plus PT. Because chronic pain is a complex, multidimensional experience that has been shown to affect multiple physical and psychosocial parameters in older adults,[29–33] the secondary aim of this study was to compare the effect of PENS plus PT with that sham PENS plus PT on outcomes that have particular relevance to older adults: physical performance, sleep, mood, and neuropsychological function.

METHODS

Subjects

Subjects were recruited via newspaper advertisement. Written informed consent, approved by the university's institutional review board, was obtained from all subjects before their participation. Subjects randomized to the clinical trial were 34 English-speaking, community-dwelling adults aged 65 and older with CLBP of at least moderate intensity. Chronic pain was operationally defined as that occurring daily or almost every day for the previous 3 months. Subject demographics are provided in Table 1.

Exclusion criteria included (1) a prominent component of radicular pain, because PENS for the treatment of sciatica would require a distinct protocol; (2) the presence of a pacemaker, because of the unknown effects of PENS on the electrical conduction system of the heart; (3) systemic anticoagulation, as a precautionary measure; (4) known spinal pathology other than osteoarthritis (e.g., a history of back surgery or trauma, vertebral compression fractures, ankylosing spondylitis, other seronegative spondyloarthropathies, carcinoma metastatic to the spine), because it is desirable to examine the efficacy of PENS for the treatment of the most common type of CLBP, that is, mechanical low back pain; and (5) active nonmusculoskeletal pain (e.g., migraine headaches, trigeminal neuralgia) or non-lumbosacral musculoskeletal pain that interferes with activity (e.g., hip pain, knee pain), because of the potential for these conditions to influence the outcome measures independently.

In addition, to eliminate confounding of the neuropsychological testing by disorders other than pain itself, subjects were excluded from participating in the study if they had a neurological disorder (e.g., traumatic brain injury with loss of consciousness for more than 60 minutes, Parkinson's disease, cerebral tumor, Alzheimer's disease or other dementing illness, prior stroke, multiple sclerosis, seizure disorder, or substance abuse) that would seriously affect the results of neuropsychological testing. Persons with alcohol intake exceeding two drinks per day were excluded, based on the National Institute on Alcohol Abuse and Alcoholism criteria of 60 drinks/month as heavy drinking and the recent findings that heavy social drinking is associated with mild to moderate cognitive deficits.[34] Individuals with severe visual or hearing impairment that would interfere with neuropsychological testing also were excluded.

Subjects were also excluded if they had medical conditions that would make performance of the repetitive lifting task (see below) potentially unsafe. These included unstable angina pectoris, greater than one unexplained syncopal episode, class III or IV congestive heart failure, oxygen-dependent chronic obstructive pulmonary disease, recurrent unexplained falls, uncontrolled hypertension, or the inability to stand independently.

Table 1. Subject Demographics

Variable	Treatment Condition: PENS + PT n = 17	Treatment Condition: Sham PENS + PT n = 17	*P*-value
Age, mean ± SD	74.1 ± 4.6	73.5 ± 5.7	.78
Sex, n			
Male	6	10	.31
Female	11	7	
Education, %			
High school graduate	4	5	.72
Some college (or trade school)	5	3	
College graduate	8	9	
Ethnicity, n			
White	16	17	.31
African American	1	0	
Current living situation, n			
Live alone	7	3	.35
Live with spouse	8	12	
Live with other family members	1	1	
Live with others (nonfamily)	1	1	
Duration of pain, years, mean ± SD	10.6 ± 11.1	16.6 ± 16.4	.24
Cumulative Illness Rating Scale, mean ± SD	15.8 ± 4.8	13.9 ± 4.7	.25
Folstein Mini-Mental State Examination, mean ± SD	29.2 ± 0.8	28.7 ± 1.0	.11
Self-rated health (4 = excellent, 0 = bad), mean ± SD	2.5 ± 0.7	2.2 ± 0.9	.18
Medications			
Opioids	2	0	.48
Other analgesics	10	7	.49

PENS = percutaneous electrical nerve stimulation; PT = physical therapy; SD = standard deviation.

Procedures

Potential exclusions were examined in two phases. Individuals were first screened over the telephone using a structured questionnaire. Of the 105 screened, 54 (51.4%) were found eligible to continue. If not excluded over the telephone, subjects were evaluated on site (University of Pittsburgh Pain Evaluation and Treatment Institute) with a history and physical examination to validate the exclusion criteria obtained by telephone, screen for dementia using the Folstein Mini-Mental State Examination (MMSE), and determine whether they were able to perform the isoinertial lifting task (see below).

If no exclusions were noted on history and physical examination and subjects scored higher than 24 on the MMSE, they underwent a posteroanterior and lateral view of the lumbosacral spine to screen for nondegenerative spinal pathology (e.g., vertebral compression fractures, lytic or blastic lesions) and to determine the safety of performing the lifting task (absence of compression fractures or malignancy). After this initial evaluation, 46 of the 50 subjects (92%) who came for evaluation met the inclusion criteria outlined above, but 12 of these 46 subjects (26%) declined further participation, with seven citing insurance reasons (the PENS treatment but not the PT component was free of charge and coverage for the PT treatment was denied by their insurance company) and the remaining five subjects citing lack of time to complete the treatments. The remaining 34 subjects (74% of eligible subjects) were randomized to a treatment group or a control/comparison group, described below. Statistical analyses for the demographic factors listed in Table 1 indicated no significant differences between the 34 subjects continuing in the study and the 12 who declined to enter treatment.

Baseline (Pre-Intervention) Assessment

All subjects (treatment and control groups) received identical baseline (pretreatment) assessments. Because pain is a multidimensional experience, instruments were selected to measure multiple major domains of the effect of chronic pain and potential treatment outcomes. These domains and the selected instruments are summarized below.

1. Demographic data included age, sex, ethnicity, and marital and education status.
2. Comorbidity was assessed using the Cumulative Illness Rating Scale,[35] based upon history and physical examination by one of the investigators (DW).
3. Pain Intensity was measured with the McGill Pain Questionnaire (MPQ) short form[36] and the Pain Severity scale of the Multidimensional Pain Inventory (MPI).[37] The MPQ measures present pain intensity and evaluates sensory and affective components of the pain experience; the Pain Severity Scale of the MPI focuses more on the average pain the subject has had in the past week and the corresponding amount of suffering experienced.

4. Pain-related disability was measured with the Roland and Morris Back Pain Disability Questionnaire[38] and the Pain Interference Scale of the MPI.[37] The Roland and Morris Scale is specific to low back pain, whereas the MPI pain interference scale is a more general measure of pain interference with performance of activities of daily living.
5. Physical performance was measured with timed chair rise (mean over five consecutive trials), an assessment of lower extremity strength, postural control, and standing balance[39] (a useful measure of functional status in older adults with CLBP because back pain can limit the ability to transfer to/from bed, chair, or commode); functional reach, a reliable and valid clinical measure of balance;[40] gait speed, time based on walking a level, straight, 50-foot course;[41] and static and isoinertial lifting, measures of physical capacity described below. These measures have been validated in younger individuals with low back pain.[42] Fourteen of the subjects had radiographic evidence of osteoporotic vertebral compression fractures, thus these individuals were deemed unsafe to perform the lifting procedures. Although all subjects performed the other physical performance tasks, only 20 performed the static and isoinertial lifting tasks (nine in the PENS plus PT group and 11 in the sham PENS plus PT group).
6. Psychosocial factors included mood, as measured using the 30-item Geriatric Depression Scale (GDS);[43] sleep, because of its demonstrated association with pain,[31,33,44] assessed using the Pittsburgh Sleep Quality Index,[45] an instrument with demonstrated test-retest reliability in older adults;[46] and the Life Control Scale of the MPI.[37]
7. Cognitive function was assessed using the MMSE to screen mental status in the pre-entry phase (see Table 1). Several laboratory studies in middle-aged individuals suggest that pain adversely affects attention and concentration,[47–49] although similar studies have not been performed in older adults. This question was explored by asking all subjects to perform the Trail Making Test Part B as a measure of attention, concentration, and mental flexibility.[50] Learning and memory were evaluated with the Hopkins Verbal Learning Test.[51]
8. Medications; all prescription and over-the-counter analgesics in current use were recorded and classified as opioids and nonopioids. The results are presented in Table 1.

To summarize the measures and evaluation of outcomes, pain intensity and pain-related disability were considered the primary outcome measures, which were used to test the primary hypotheses, with the remainder of the measures considered secondary outcomes.

Description of Lifting Tasks

Static Lifting Task

Each subject's maximum voluntary static lifting strength was measured using a force gauge (Mark-10, Chatillon, Greensboro, NC) mounted on a platform to determine the load level for the isoinertial lift. Subjects were instructed to assume a bilateral symmetrical leg lift (knees bent, head and chest up) with forearm in supination and the handle adjusted to knee height. The subject was told that the handle will not move during the test and that the gauge will be measuring the amount of force they can exert. Subjects were instructed to use a steady pull with increasing force, avoid jerky movements, and exhale during each of the three test trials. There was a 30-second rest period between the three readings to enable the subject to return to a standing position. The mean of the maximum force recorded from the force gauge was used to represent maximum voluntary static lifting strength.

Isoinertial Repetitive Lifting Task

This was conducted with the BTE Work Simulator (Baltimore Therapeutic Equipment Co., Baltimore, MD) with the subject standing on a force platform. The Work Simulator, which has been modified by engineers at BTE for this program of research, is a computerized device that maintains constant torque resistance during task execution and measures torque, degrees of rotation, velocity of rotation, and time for each repetition of the task (and therefore the dynamic or static power the subject generated during the task). It was selected for this study because it can be computer controlled, permits unrestrained testing of a variety of movement patterns, and provides appropriate output signals for computer analysis. During the test, the subject lifted a handle from knee to waist level while the Work Simulator applied a force equal to 40% of the subject's measured maximum lifting strength to the handle. Lifts were performed at four per minute for 20 minutes, until the subjected elected to stop or until the occupational therapist supervising the procedure (SL) elected to stop the testing for reasons of safety.

Lift-Task-Dependent Measures

Subjects' performance during the repetitive lifting task was characterized by static lifting strength and endurance, defined as the number of lifts performed.

Intervention Phase

A simple computer-generated randomization scheme was used to assign an equal number of subjects to the treatment and control/comparison groups. All subjects were seen twice a week for 6 weeks. Both treatment and control subjects received PT. The treatment group received PENS, and the control group received sham PENS (application of acupuncture needles without the delivery of electricity). One of the investigators (RG), who is a licensed acupuncturist and trained in PENS, administered all PENS and sham PENS treatments. No medication changes were enacted during the 6 weeks of treatment.

Percutaneous Electrical Nerve Stimulation

PENS was administered according to a previously reported technique.[13] Application of acupuncture needles and electrical stimulation occurred at the appropriate dermatomal, myotomal, and sclerotomal levels. Stimulation frequencies ranged from 2 to 200 Hz; the progression from session to session was guided using a structured protocol, as shown in Figure 1. Intensity of the electrical stim-

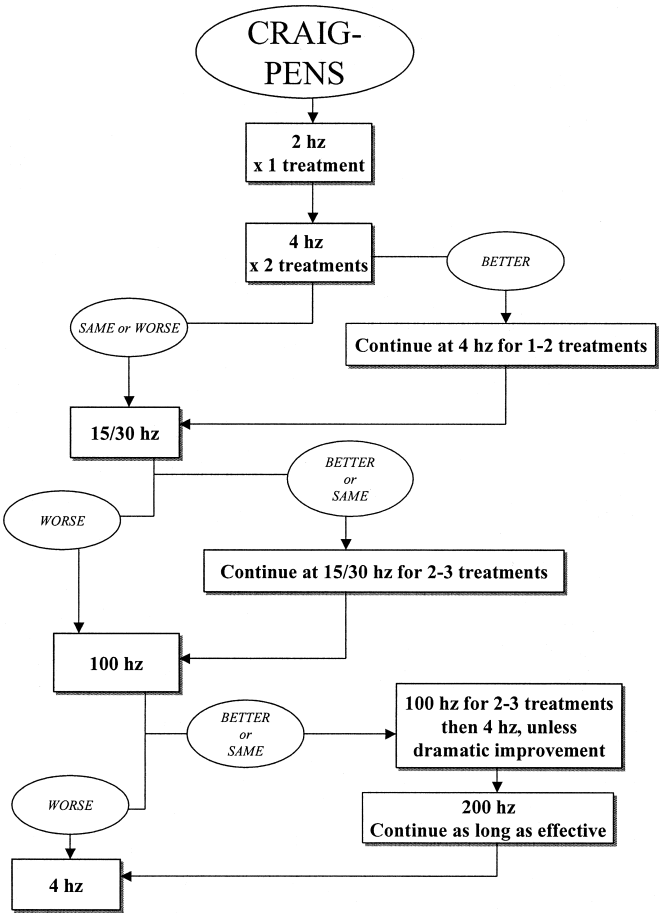

Figure 1. Protocol used for the administration of percutaneous electrical nerve stimulation (PENS). Modified from Taylor SM. Craig-PENS. J Aust Med Acupuncture Soc 1997;15:22–28.

ulation was maintained below the pain threshold. All treatment sessions were 30 minutes long.

Sham PENS

Sham PENS was administered to the control/comparison group. Acupuncture needles were applied using a technique identical to that used in the PENS group, but no electrical stimulation was provided. As with the PENS group, all sessions were 30 minutes long.

Physical Therapy

Physical therapy treatment session goals were established mutually with the patient and the treating therapist. Therapists were masked to the subject's randomization group. The treatment sessions were structured to meet these goals and were presented in a standardized sequence that promoted physical reconditioning, management of pain flares, a broad understanding of the pathology of pain, and the importance of active participation to manage pain. Modalities and manual therapy were used to facilitate subjects' ability to perform recommended exercises. Exercise programs were created to address stretching and flexibility of the low back and the generalized deconditioning that is often associated with activity avoidance due to chronic pain. Subject education occurred throughout the treatment sessions and addressed the topics of the anatomical and pathological bases for the pain condition, importance of active participation of the subject in managing the pain, and the use of flare management techniques (e.g., modalities, exercise, compression techniques, or positional distraction).

Evaluation of Treatment Outcome

To determine the immediate effects of the intervention, all data collected in the baseline phase, with the exception of demographics, roentgen rays, and comorbidity, were repeated within 1 week of completion of the intervention (posttreatment assessment). Three months after the completion of the intervention (3-month follow-up assessment), all measures were again repeated. The purpose of the 3-month follow-up was to determine the magnitude of the maintenance of the effect observed at the time of the posttreatment assessment.

Potential bias regarding treatment outcome was minimized by the fact that the physical therapist treating all subjects was masked to the treatment condition, that is, whether the subject had been randomized to the PENS or the sham PENS group. Subjects were instructed not to discuss their group assignment with the treating therapist so as to uphold masking. Research assistants collecting the pain, cognitive, psychosocial, and physical function outcome data were similarly masked. Specifically, subjects were instructed not to discuss their treatment with the assistants, the assistants were masked to the randomization plan, and subjects' medical records were not available to them during the study. The same individual administered PENS and sham PENS, thus this person was not masked. Because the two procedures involved the same amount of clinician-subject contact time, any nonspecific effects related to contact time were eliminated.

Data Analysis

The basic experimental design and corresponding data analyses represented a one-between subjects (PENS plus PT vs sham PENS plus PT) and one-within or repeated factor (pre, post, and follow-up assessments) crossed factorial design, with multiple dependent outcome measures. A multivariate or doubly multivariate (multiple qualitatively distinct measures at multiple times) approach to repeated measures,[52,53] based on the unweighted general linear model, was used to test for pre/post-follow-up changes between the two treatment groups. This approach provides better control for experimentwise error rates and avoids the compound symmetry assumption necessary for the univariate repeated measures approach. Primary analyses were based on a priori multivariate contrasts designed to test the primary hypotheses. Significant interactions were interpreted using simple main effects; the Tukey-Kramer method[54] of controlling type I error rates was used for between-subject posthoc comparisons; and improved, more-powerful Bonferroni-type multiple comparison procedures[55] were used to control type I error rates for within-subject comparisons. Before conducting the primary statistical analyses, the statistical models for violations of heteroscedasticity of errors and nonlinearity using standard graphical methods were evaluated. Also, the data analyses adhered to an intent-to-treat model. One subject each in the PENS plus PT group and the sham PENS

plus PT group dropped out of treatment, and one subject in the PENS plus PT group was lost to follow-up. A conservative approach was followed and used their pretreatment scores in the data analyses, thus assuming they were treatment failures.[56] Because of the small sample size, exact probability chi-square analyses, computed with the Stat Xact program (CYTEL Software Corporation, Cambridge, MA), were used to analyze dichotomous and ordinal measures. $P < .05$ was used to indicate statistical significance.

RESULTS

Table 1 presents patient demographics by treatment group and the *P*-values associated with chi-square or analysis of variance tests that evaluated potential differences between the two treatment groups. As displayed in Table 1, the groups did not differ significantly on any of these demographic variables, indicating that the simple randomization procedures used were effective.

Primary Outcome Measures

Pain Intensity

The results of a doubly multivariate repeated measures multivariate analysis of variance (MANOVA) with the two pain measures as the dependent measures are displayed in Table 2. Overall, this analysis indicated statistically significant differences between groups, over time, and a group-by-time interaction, suggesting that the two groups changed differentially across the three assessments. The group-by-time interaction for the McGill Pain Questionnaire is plotted in Figure 2. Multivariate contrast analyses to interpret further the significant interaction indicated that the PENS plus PT group displayed significant reductions in pain intensity measures from pre- to posttreatment ($P < .001$), but the sham PENS plus PT group did not ($P = .94$). As displayed in Table 2, the reductions in pain intensity were maintained from posttreatment to the 3-month follow-up by the PENS plus PT group; that is, the posttreatment and 3-month follow-up scores were not significantly different ($P = .84$).

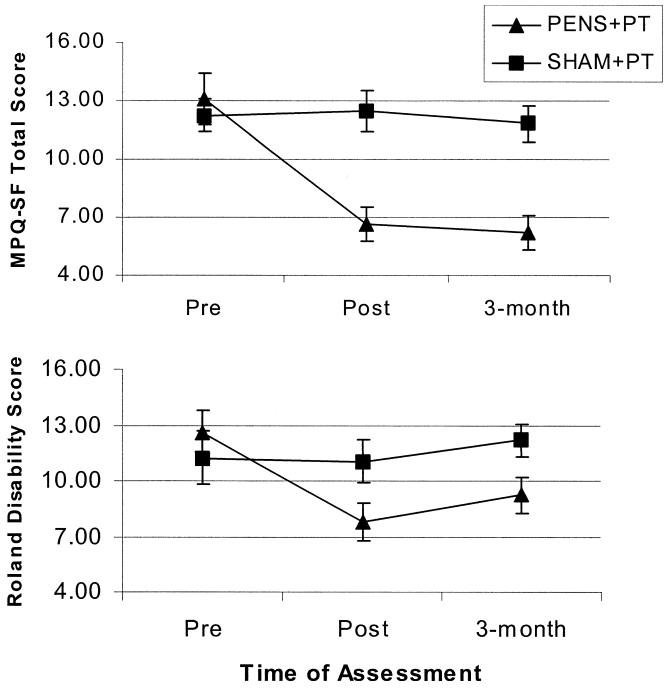

Figure 2. Means and standard error of the mean by treatment group and time of assessment for the McGill Pain Questionnaire (top) and for the Roland Disability Scale (bottom).

Pain-Related Disability

Table 2 presents the results for the measures used to evaluate changes in perceived pain-related disability. As with

Table 2. Results for Primary Outcome Measures for Pre- and Posttreatment and Follow-Up Assessments by Treatment Condition

Measure/Treatment Condition	Mean ± Standard Error of Mean Time of Assessment			MANOVA Results *P*-value for *F* test		
	Pre	Post	Follow-Up	Group (G)	Time (T)	G × T
Pain intensity				.02*	.002*	.004*
McGill Pain Questionnaire				.04	.005	.009
PENS + PT	13.06 ± 1.31	6.66 ± 0.87	6.19 ± 0.88			
Sham PENS + PT	12.24 ± 1.69	12.47 ± 2.04	11.82 ± 1.90			
MPI Pain Severity Scale				.003	.012	.025
PENS + PT	3.21 ± 0.25	2.00 ± 0.20	2.16 ± 0.30			
Sham PENS + PT	3.28 ± 0.28	3.22 ± 0.23	3.10 ± 0.16			
Pain-related disability				.29*	.028*	.012*
Roland Disability Scale				.26	.042	.034
PENS + PT	12.63 ± 1.13	7.81 ± 1.02	9.25 ± 1.08			
Sham PENS + PT	11.24 ± 1.47	11.06 ± 1.17	12.18 ± 1.21			
MPI Pain Interference Scale				.57	<.001	.036
PENS + PT	3.52 ± 0.37	2.44 ± 0.33	2.61 ± 0.26			
Sham PENS + PT	3.30 ± 0.37	3.10 ± 0.40	2.97 ± 0.37			

*Significance levels for doubly multivariate analysis of variance (MANOVA) (multiple measures at multiple times) results for primary outcome constructs.
PENS = percutaneous electrical nerve stimulation; PT = physical therapy; MPI = multidimensional pain inventory.

the pain intensity measures, the doubly multivariate repeated measures MANOVA indicated a significant group-by-time interaction (plotted in Figure 2 for the Roland Disability Scale). Multivariate contrast analyses indicated that the PENS plus PT group displayed significant reductions in pain-related disability from pre- to posttreatment ($P = .002$), but the sham PENS plus PT group did not ($P = .81$). As can be seen in Table 2, although there was some increase in pain-related disability ratings for the PENS plus PT group at follow-up, these follow-up measures were not significantly higher than their posttreatment scores ($P = .26$), indicating that the effect was maintained at the 3 months follow-up.

Secondary Outcome Measures

Physical Performance

Table 3 presents the results for the four measures used to evaluate treatment outcomes for directly observed physical capacities. Doubly multivariate analyses could not be performed because of sample size differences across these measures. (As noted above, only 20 of the subjects were able to safely perform the lifting tasks.) MANOVA results by measures (Table 3) indicated that (1) no significant differences were found for the functional reach task; (2) a significant group-by-time interaction occurred for the chair rise task, with the PENS plus PT group demonstrating significant reductions in performance times from pre- to posttreatment ($P = .011$), which were maintained from post to follow-up ($P = .62$), but the sham PENS plus PT group showed no changes over time for the chair rise task ($P = .41$); (3) significant changes over time were found for gait speed, with both the PENS plus PT group ($P = .045$) and the sham PENS plus PT group ($P = .032$) displaying significant reductions in walking times after treatment; (4) no significant group or time differences were found for static lifting strength; and (5) a significant group-by-time interaction was found for the number of dynamic lifts per-

Table 3. Secondary Outcome Measures for Pre- and Posttreatment and Follow-Up Assessments by Treatment Condition

Measures/Treatment Condition	Means ± Standard Error of Mean Time of Assessment			MANOVA Results *P*-values for *F* tests*		
	Pre	Post	Follow-Up	Group (G)	Time (T)	G × T
Physical performance						
Functional reach, inches				.73	.64	.15
PENS + PT	10.33 ± 0.86	12.46 ± 1.94	11.73 ± 0.33			
Sham PENS + PT	12.16 ± 0.62	12.07 ± 0.54	11.29 ± 0.83			
Chair rise, seconds				.30	.81	.029
PENS + PT	3.69 ± 0.13	3.12 ± 0.17	3.19 ± 0.18			
Sham PENS + PT	3.42 ± 0.38	3.77 ± 0.21	3.75 ± 0.27			
Gait speed, seconds				.07	.003	.88
PENS + PT	17.60 ± 0.82	16.34 ± 0.70	16.45 ± 0.81			
Sham PENS + PT	15.51 ± 0.80	14.45 ± 0.67	14.35 ± 0.79			
Static lifting strength, kg				.35	.24	.99
PENS + PT	36.75 ± 5.11	40.00 ± 5.60	43.62 ± 3.25			
Sham PENS + PT	44.42 ± 6.52	47.76 ± 6.65	51.23 ± 5.85			
Number of dynamic lifts				.12	.10	.034
PENS + PT	34.00 ± 4.51	47.13 ± 2.12	47.00 ± 1.67			
Sham PENS + PT	34.58 ± 4.98	34.17 ± 5.22	30.80 ± 5.11			
Psychosocial factors				.60*	.023*	.041*
Geriatric Depression Scale				.75	.11	.024
PENS + PT	6.81 ± 1.73	3.44 ± 0.90	4.11 ± 0.87			
Sham PENS + PT	5.00 ± 1.09	5.50 ± 1.22	5.41 ± 1.37			
Sleep Quality Index				.31	.052	.29
PENS + PT	5.38 ± 1.15	3.56 ± 0.63	5.19 ± 0.85			
Sham PENS + PT	6.59 ± 0.87	5.35 ± 0.88	5.59 ± 0.86			
MPI Life Control Scale				.039	.027	.016
PENS + PT	4.22 ± 0.21	5.10 ± 0.13	5.08 ± 0.14			
Sham PENS + PT	4.32 ± 0.28	4.23 ± 0.21	4.34 ± 0.27			
Cognitive function				.80*	.95*	.55*
Hopkins Verbal Learning				.068	.86	.78
PENS + PT	21.75 ± 1.12	21.29 ± 1.01	22.00 ± 1.05			
Sham PENS + PT	19.24 ± 1.35	19.06 ± 1.11	19.00 ± 1.10			
Trail Making B Test, seconds				.99	.94	.54
PENS + PT	91.63 ± 7.76	98.55 ± 14.11	94.43 ± 7.81			
Sham PENS + PT	97.47 ± 8.76	94.06 ± 8.76	92.82 ± 6.75			

* Significance levels for doubly multivariate analysis of variance (MANOVA) (multiple measures at multiple times) results for secondary outcome constructs.
PENS = percutaneous electrical nerve stimulation; PT = physical therapy; MPI = multidimensional pain inventory.

formed, with the PENS plus PT group demonstrating a significant increase in the number of lifts performed from pre- to posttreatment ($P = .041$), which was maintained from post to follow-up ($P = .97$), but the sham PENS plus PT group showed no changes over time for the dynamic lifting task ($P = .71$).

Psychosocial Factors

Table 3 summarizes the findings for the three measures used to evaluate changes in psychosocial functioning. As can be seen, the doubly multivariate test indicated a significant group-by-time interaction. Multivariate contrasts indicated that the PENS plus PT group displayed significant pre- to posttreatment changes for the psychosocial measures ($P = .027$), but the sham PENS plus PT group did not ($P = .47$). Subsequent analyses for the PENS plus PT group indicated that significant pre- to posttreatment changes were maintained from post to follow-up for the GDS ($P = .27$) and for the MPI Life Control Scale ($P = .92$) but not for the Sleep Quality Index, which demonstrated a significant increase from post to follow-up ($P = .021$).

Cognitive Function

Table 3 displays the findings for the two measures used to evaluate cognitive function. As can be seen, no significant differences between groups or across time of assessment were found.

DISCUSSION

The study described in this paper represents the first comprehensive examination of a complementary medicine intervention for CLBP in older adults. The preliminary findings suggest that PENS is a promising treatment modality, as evidenced by its sustained effects on the primary outcome measures (pain intensity and disability) and some of the secondary measures (psychosocial function and two tests of physical performance—timed chair rise and lifting endurance). The improvement in these measures supports their inclusion as outcomes in future clinical trials on the effects of PENS on CLBP in older adults.

Even though none of the subjects were clinically depressed and did not meet criteria for depression based upon their GDS scores, individuals treated with PENS plus PT improved significantly more on their GDS scores immediately after treatment and at 3-month follow-up than those in the sham PENS plus PT group. The association between pain and clinical depression is well documented in the literature.[30,32,57–60] A relationship between pain and modestly elevated GDS scores without clinical depression has also recently been demonstrated.[61] These study results further extend these findings by demonstrating in older adults without clinical depression that GDS scores can be lowered via treatment focused on analgesia. Additional longitudinal studies are needed to determine the influence of early, effective pain management on the prevention of clinical depression.

Although substantive improvement in many important functional domains was demonstrated in the study, several of the outcome measures did not change. Functional reach and sleep most likely remained stable because of ceiling effects. Static lifting strength also remained constant, probably because of the relatively short duration of the physical therapy conditioning program. In addition, the physical therapy program was oriented toward flexibility and endurance training rather than strength training. As a result, gait speed improved modestly in both groups.

Attention and concentration, as measured using the Trail Making Test Part B and the Hopkins Verbal Learning test, did not improve in association with reduction in pain intensity. Several studies that have been conducted with younger individuals indicate an association between pain intensity and laboratory-based measures of attention.[47–49] Several factors may have caused this study's inability to demonstrate such an association in older adult subjects with CLBP. The subjects' pain severity may have been of insufficient magnitude to adversely affect cognitive function. Alternatively, the degree of improvement in pain may have been insufficient to result in measurable improvement in cognitive function. Finally, the baseline cognitive function of participants before treatment may have been outstanding and therefore created a ceiling effect. However, examination of age-matched norms[51] norms for the Hopkins Verbal Learning Test and Trail Making Test Part B scores indicated that this sample had only average performances, thus suggesting that a ceiling effect did not appear to be a mitigating factor. Clearly additional studies are needed to determine the influence of chronic pain on neuropsychological function in community-dwelling older adults, and whether effective pain management can affect cognitive function.

Some may question the degree to which the placebo effect influenced the study results. PENS involves the delivery of an electrical stimulation that is clearly perceptible, making it difficult to truly mask subjects to their randomization group. However, the persistence of the treatment response across multiple parameters at 3 months of follow-up makes the role of the placebo effect less likely. Treatment expectancy or treatment credibility was not evaluated as part of this research study but should be included in future investigations to help determine the degree to which belief in the efficacy of the therapy being delivered influences outcome.

Creating robust control groups for acupuncture studies poses a number of challenges. There is evidence that acupuncture needles placed in nonacupuncture points lead to pain reduction because of stimulation of endorphin release via a mechanism called diffuse noxious inhibitory control.[62] Some investigators therefore advocate using a comparison group (e.g., massage therapy) in acupuncture studies rather than a control group.[12] Other control group designs, such as using different electrical frequencies or placing the acupuncture needles in different locations (not in the lower back), were considered but were not chosen for the following reasons. The efficacy of PENS has not been tested at all electrical frequencies, thus the random choice of a "sham" frequency would be guided by guesswork rather than science and the possibility of an independent therapeutic effect could not be assured. Placement of acupuncture needles at sites other than the low back would apparently diminish the credibility of the intervention; therefore this type of control group also would be suboptimal.

Additional studies are needed to expand and refine the results of this preliminary investigation. It was surprising

that PT alone (sham PENS plus PT) resulted in no apparent therapeutic benefit. Perhaps PENS facilitated compliance with the home exercise component of the PT program, and improvement in the PENS group was actually a result of the combined effects of PENS and PT. In addition, the PT program administered contained some primary pain management components such as instruction in how to manage pain flares and the use of nonpharmacological analgesic modalities (e.g., heat, ice). The true efficacy of PENS therefore may have been diluted by these factors. Future studies should use a functional restoration program that does not contain primary pain management components and should explicitly examine the influence of compliance with home exercise on treatment outcomes. In addition, to disentangle the effects of analgesia and exercise and examine the true efficacy of PENS, this modality should be examined with and without an intervention targeted at functional restoration. Studies with larger sample sizes and longer duration of treatment follow-up also will allow more-definitive conclusions to be drawn regarding the efficacy of PENS.

To optimize the risk-benefit ratio of pain-management interventions for older adults, the use of safe, nonpharmacological modalities such as PENS must become more routine. For this to happen, rigorous trials that examine the efficacy of complementary-medicine interventions must be aggressively pursued. Convincing data are needed to support the widespread use and reimbursement for the implementation of these important treatment options. Only then will the array of credible pain treatment options be appropriately expanded and, therefore, will older adults be given the additional hope for pain relief that they deserve.

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