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GENERAL SECTION

Original Research Articles

Day-to-Day Changes of Auricular Point Acupressure to Manage Chronic Low Back Pain: A 29-day Randomized Controlled Study

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Abstract

Objective. The purpose of this study was to determine the effects of a 4-week auricular point acupressure (APA) treatment on chronic low back pain (CLBP) outcomes and examine the day-to-day variability of CLBP in individuals receiving APA for CLBP over 29 days.

Design. This was a prospective, randomized controlled trial (RCT). Data were collected at baseline, during each of the four office visits for APA treatment, after the completion of the 4-week intervention, and 1 month after the last treatment. A daily diary was given to each participant to record his or her APA practices, analgesic use, and pain intensity.

Interventions. APA was used to manage CLBP. The participants received one APA treatment per week for 4 weeks.

Patients and Setting. Sixty-one participants with CLBP were randomized into either a real APA or sham APA treatment group. Participants were recruited from primary care offices and clinics or through the Research Participant Registry at the University of Pittsburgh.

Results. Among participants in the real APA group, a 30% reduction of worst pain was exhibited after the first day of APA treatment, and continuous reduction in pain (44%) was reported by the completion of the 4-week APA. This magnitude of pain reduction reached the clinically significant level of improvement reported in other clinical trials of chronic pain therapies. Analgesic use by participants in the real APA group also was reduced compared with use by participants in the sham group.

Conclusion. This study shows that APA is a promising pain management strategy that is not invasive and can be self-managed by participants for CLBP. Given the day-to-day fluctuation in ratings, the tighter ecologic assessment of pain scores and other treatment parameters are an important pragmatic aspect of the design of chronic pain studies.

Key Words. Auricular Point Acupressure; Chronic Low Back Pain; Pain Intensity; Analgesic Use

Introduction

Patient-reported pain intensity based on recall over days or weeks is often used in clinical and research evaluation [1,2]. However, fluctuations of pain intensity for chronic low back pain (CLBP) are common and likely to occur during treatment. Patient recall of pain intensity does not capture the dynamic fluctuation of pain in everyday life and impedes the effectiveness of pain management interventions. The variability of pain intensity may play a vital role in patient coping and management of pain [3].

The prevalence of CLBP, defined as back pain lasting 3 months or longer, is 28% in adults in the United States [4]. Between 11% and 12% of those suffering CLBP are disabled because of it [5,6]. The effects of CLBP place an enormous burden on society and healthcare systems in the United States, as reflected by medical care costs and disability-related loss of productivity and wages [6–8]. A variety of approaches (i.e., analgesics, education, exercise, spinal manipulation, massage, or acupuncture) have been suggested as reasonable modalities for management of CLBP, but these treatments have had limited efficacy [9]. Analgesics are the most common methods used to treat CLBP but are associated with a variety of adverse side effects [10,11]. For example, the need for pain medication can escalate as tolerance develops, resulting in dependence and the potential for drug addiction [10,11]. Improved nonpharmacological pain management is needed—especially for those suffering from CLBP.

Auricular Point Acupressure (APA)

APA is one form of auricular therapy that uses botanical seeds (or pellets) taped onto acupoints on the ear to produce acupuncture-like effects. APA originated in China more than 2,000 years ago and was later redeveloped by the French neurosurgeon Dr. Paul Nogier in 1957 [12,13]. An ear zone system with standardized nomenclature has been established by the World Health Organization (WHO) [14]. This system incorporates auricular anatomy and proven therapeutic effects, and it has been accepted internationally [14]. The stimulation of specific points on the ear by applying pressure to them with the thumb and forefinger influences a distinct anatomical region of the body, which can engender therapeutic effects [12–14]. The underlying theory of auricular therapy posits that nerves in the outer ear correspond to specific areas of the brain, and these areas have a reflex connection with specific parts of the body [12,13]. This connection has been validated by functional magnetic resonance imaging (fMRI) [15]. The treatment of points on the ear can stimulate the brain to correct its pathological reflex centers [15], change levels of serum pro- and anti-inflammatory cytokines [16], and induce reflex reactions in the body to relieve body pathology [12,13,17].

Studies of Auricular Therapy for Pain Management

Studies using auricular therapy (including acupuncture or APA on the external ear) have shown promising effects in pain management, which include immediate relief for migraine pain [18], burn pain [19], perioperative pain during oocyte aspiration [20], post-surgery pain [21–24], distal extremity pain [25], hip fracture pain [26], and chronic pain [27–30]. In a recent meta-analysis of 13 randomized clinical trials of auricular therapy for pain management, auricular therapy provided significant pain relief when compared with a sham or control group [31]. The overall standardized mean differences (SMD) was 1.59 (95% CI [−2.36, −0.82]) for the 13 trials, which included a total of 806 participants, indicating that, on average, the mean decrease in pain score for auricular therapy group was 1.59 standard deviations greater than the mean decrease for the sham control group [31]. These studies provide promising evidence concerning the efficacy of APA for pain relief; however, these studies were limited by small sample sizes, inadequate blinding procedures, and the lack of rigorous study design.

We have applied APA to manage CLBP, and our data has shown preliminary evidence of not only immediate CLBP relief (40% reduction in pain intensity 1 day after APA) [32], but also lasting effects on CLBP (75% pain relief and 45% better physical function after a 4-week APA treatment, which were statistically significant compared with the sham APA group) [33]. Moreover, APA is feasible in older adults with CLBP [34]. Participants exhibited changes in inflammatory cytokines [16], decreased pain catastrophizing, and reduced fear avoidance after a 4-week APA, compared with participants in the sham APA group [33]. In this article, we report the effects of a 4-week APA treatment on CLBP over time, particularly focusing on day-to-day variability of pain intensity across a period of 29 days, in which the participants received one APA treatment each week.

Methods

Our study used a prospective, randomized controlled trial (RCT), repeated measurements design. Participants were randomized into either a real APA group or a sham APA group after baseline assessment was completed. Each participant received a total of four APA treatments (one per week over 28 days) according to his or her assigned group. Data were collected at baseline, during each of the four office visits for APA treatment, after the completion of the 4-week APA, and once, 1 month after the last treatment. A daily diary was given to each participant to record his or her APA practices, analgesic use, and pain intensity. The complete details of the study design, sample and data collection are described in an article by the current authors [33].

Participants

Participants were recruited to the study if they met the following inclusion criteria: aged 18 years or over; able to read and write English; has CLBP of at least 3 months duration with pain intensity greater than any

other body part; willing to commit to weekly study visits for 4 weeks and two follow-up visits (i.e., end-of-intervention and 1 month later) (data is not reported here but available upon request); and had pain intensity of 4 or greater on an 11-point numerical pain scale. Participants were excluded from the study if they had an inflammatory, malignant, or autoimmune disease; a compression fracture caused by osteoporosis, spinal stenosis, spondylolysis, spondylolisthesis, or fibromyalgia—these conditions might confound treatment effects or interpretation of results; and/or an allergy to the tape used to affix the APA seeds onto the outer ear. Institutional Review Board (IRB) approval from the University of Pittsburgh was obtained before conducting the study.

Recruitment and Setting

Participants were recruited from three sources: University of Pittsburgh Medical Center (UPMC) primary care offices and clinics; individuals who had completed a prior study of a mind-body intervention for CLBP conducted by the co-author (NM); and the Clinical and Translational Science Institute (CTSI) Research Participant Registry at the University of Pittsburgh. Potential participants who expressed interest in the study were contacted by the study coordinator by phone, and she explained the study in detail, screened for eligibility, and scheduled a clinic visit if appropriate.

Procedure

After IRB approval, the study was conducted at the University of Pittsburgh, School of Nursing. During the participant's first clinic visit, informed consent and baseline assessments were obtained. Participants were assigned with equal allocation to either the real APA group or the sham APA group using computer-generated simple randomization. After group assignment, participants received their first APA treatment. All of the participants received one treatment each week for 4 weeks. The first visit lasted from 1.5 to 2 hours, and the follow up visits lasted approximately 30 minutes. All participants received free parking and a payment of $50 when the study was completed. All participants were blinded: they were told that different kinds of APA were being examined in the study. The first author who was also the therapist was not blinded because she provided the APA for all of the participants; however, the data collector was blinded regarding group assignment.

APA Treatment Protocol

The APA treatment protocol used in this study has been described in detail in one of our earlier publications [35]. The selection of specific points on the ear for treating CLBP centers on identifying the *active corresponding ear points* among all the points located in a particular ear zone related to the lower back [35]. These active corresponding points were identified by our auricular diagnosis, which includes visual inspection, tenderness testing, and auricular electrical detection [36]. The Chinese Standard Ear-Acupoints Chart was used as a guide to locate the active ear points for CLBP [14]. For the real APA group, the five places that received acupressure included points within the two zones for LBP, located on the front and back of the ear, and three points known for alleviating stress and pain (i.e., *shenmen, sympathetic*, and *nervous subcortex*) [35]. Three pieces of waterproof tape (manufactured by AMIRTC) with two Vaccaria seeds (natural, nontoxic, botanical seeds with diameters of approximately 2 mm) each were needed to sufficiently cover each low back zone on the front and back of the ear. For the sham APA group, the five points on the ear used for treatment included *mouth, stomach, duodenum, internal ear*, and *tonsil*. These ear points were chosen for the sham APA treatment for two reasons. First, they not only were distinct from the zones of the ear (and the points therein) associated with lower back pain, but also correspond to body regions in which the participant was pain-free. Second, they were equivalent in number to those points used in the real APA treatment group.

Weekly cycles included treatment for 5 days, followed by 2 days with no seeds on the ear. Participants could shower and wash their hair during the treatment. A point finder was used to locate the ear points. After seed placement, the therapist demonstrated to the participants how to apply pressure to the seeds with the thumb and forefinger after which the participants did the pressing themselves. Moderate pressure was used for therapy. Participants were told to press the seeds three times per day (i.e., morning, noon, and evening) for 3 minutes each time (i.e., 9 minutes total), even if they were not experiencing any target symptoms. Participants were also instructed to remove the tape and seeds after 5 days, so that the ear was free of tape for 2 days each week. This minimized the risk of an allergic reaction to the tape and allowed the acupoints to recover and restore sensitivity prior to the next treatment. Bilateral (i.e., on both ears) active corresponding points were identified and used for treatment. The study participants were blinded regarding group assignment (i.e., real and sham groups). The therapist (CHY) was not blinded.

Measurements

Data reported in this manuscript were gathered from the daily diary. The participants were asked to fill out the daily diary by the end of each day. The daily diary comprised the following items:

1. *APA practice* targeted how the participants practiced APA at home, which including the frequency of pressing the taped seeds, the amount of time the seeds were pressed, and any adverse effects of APA practice.
2. *Three items of pain intensity* were drawn from the Brief Pain Intensity-short form (BPI-sf) [37], which included worst pain, average pain, and current pain.

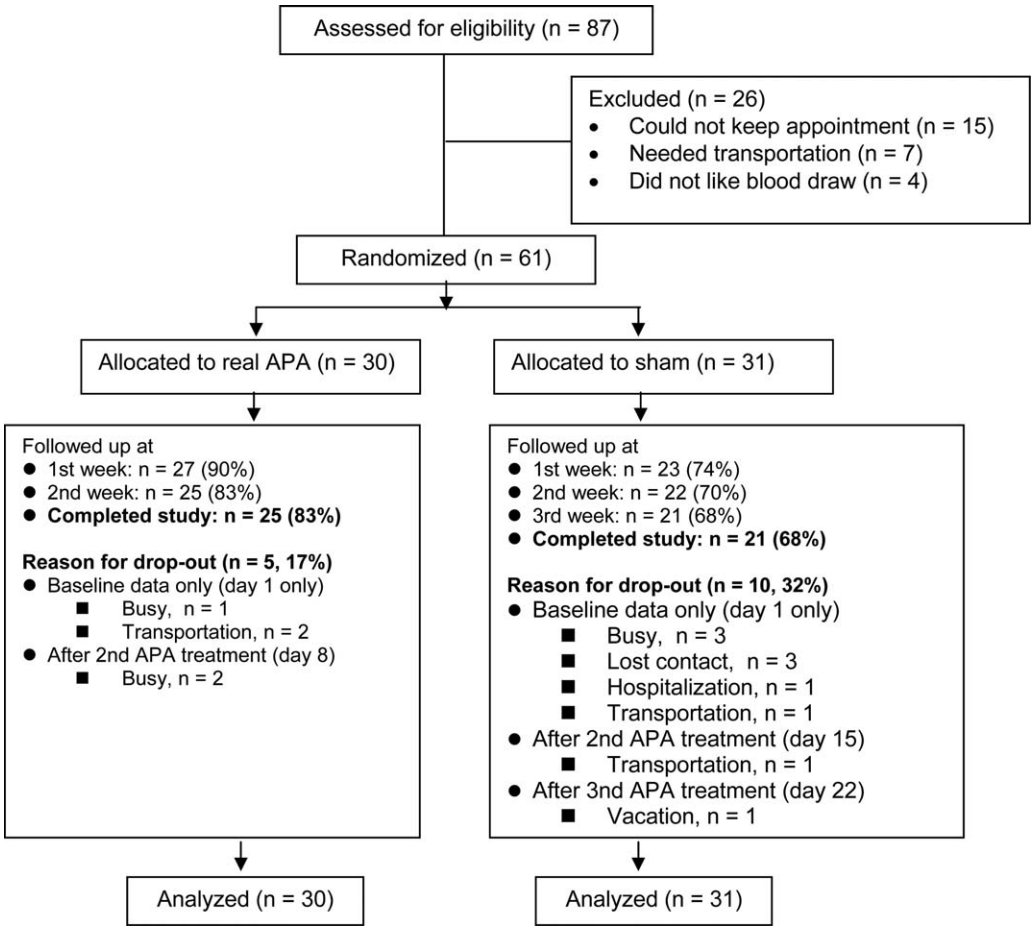

Figure 1 Flow chart of patient recruitment.

3. *For daily analgesic use*, the Medication Quantification Score Version III (MQS III) [38] was used to compute a single numeric value for a participant's pain medication profile, which was based on a participant's pain medication profile used in the previous 24 hours, according to drug class, dosage, and detriment (risk). This score was based on the subject's use of WHO level 1–3 analgesic drugs, coanalgesic drugs (i.e., tricyclic antidepressants and antiepileptics), and other drugs such as benzodiazepines or muscle relaxants. A decreasing MQS III score was correlated with improved patient outcomes and decreases in adverse side effects [38]. The MSQ III has been used successfully in other clinical trials [39–41].

Additionally, a question was used to collect demographic information (e.g., age, marital status, education level, living arrangements, and ethnicity) and health history (e.g., disease diagnosis, chronic condition, related medication, and adjunct pain treatments used).

Data Analysis

To examine the true effects of the APA between groups, two types of analyses were conducted for outcomes at baseline and end-of-intervention (EOI): intent-to-treat (ITT) analysis, using the data of all participants, and per-protocol (PP) analysis, which included only those participants who adhered to the APA. Missing values for any outcome variables were replaced by the last available data before the participant was lost to follow-up for ITT. Descriptive statistics were used for the demographic characteristics of all participants in both groups. Group comparisons for demographic characteristics were analyzed using the pooled-*t* test (for continuous variables) or chi-squared test (for categorical variables). Due to the findings of ITT and PP were similar without statistical significance, only ITT is included for advanced statistical analyses.

To examine the trajectory of pain intensity change, the joinpoint regression modeling approach [42] was used to estimate the linear trend of pain improvement in percentages of pain score over time. The model was constructed by fitting a linear regression to the improved percentage of pain intensity using calendar day (i.e., the day after receiving the APA treatment) as a regression predictor. This approach can analyze trends with different lines connected together at certain joinpoints, and

Table 1 Demographic characteristics of the participants (n = 61)

	Mean (SD) or n (%)		
	Real (31)	Sham (30)	P/χ^2
Age			
Mean (SD)	60.97 (17.44) (20–82)	65.61 (16.04) (21–90)	0.91
Gender, n (%)			
Male	10 (33.3%)	10 (32.3%)	0.93
Female	20 (66.7%)	21 (67.7%)	
Race/ethnicity, n (%)			
White	26 (86.7%)	25 (80.6%)	0.73
Black/African American	4 (13.3%)	6 (19.4%)	
Marital status, n (%)			
Married or living with partner	14 (46.7%)	13 (42.0%)	0.78
Divorced or widowed	10 (33.4%)	11 (35.5%)	
Never married	6 (20%)	5 (16.1%)	
Employment situation			0.67
Working (full time)	6 (20%)	4 (12.9%)	
Working (part time)	2 (6.7%)	2 (6.5%)	
Not employed	4 (13.2%)	6 (19.4%)	
Retired	15 (50%)	14 (45.1%)	
Others	3 (10%)	5 (16.2%)	
Education level			
<11th grade	2 (6.7%)	2 (6.5%)	0.62
High school	5 (16.7%)	4 (12.9%)	
Technical or vocational school	2 (6.7%)	2 (6.5%)	
College and graduate Missing	21 (70.1%)	21 (67.7%) 2 (6.5%)	
Estimated income before taxes			0.25
Less than $10,000	5 (16.7%)	7 (22.6%)	
$10,000 to $19,999	2 (6.7%)	5 (16.1%)	
$20,000 to $39,999	8 (26.7%)	2 (6.5%)	
$40,000 to $59,000	6 (20%)	7 (22.6%)	
$60,000 to $100,000	3 (10%)	5 (16.1%)	
More than $100,000 Missing	3 (10%) 3 (10%)	1 (3.2%) 4 (12.9%)	
Medical diagnosis related to back pain			
Osteoporosis	3 (10%)	4 (12.9%)	
Osteoarthritis	9 (30%)	9 (29%)	
Scoliosis	4 (13.3%)	5 (16.1%)	
Kyphosis	1 (3.3%)	0 (0%)	
Discherniation	6 (20%)	7 (22.6%)	
Spinal stenosis	8 (26.7%)	13 (41.9%)	
Spondylitis	1 (3.3%)	0 (0%)	
Spondylosis	3 (10%)	0 (0%)	
Current pain medication use			
Yes	13 (43.3%)	14 (45.2%)	
No	17 (56.7%)	17 (54.8%)	0.89

each joinpoint represents a significant change in the slope of the trend. A permutation test determined the best number of joinpoints in the final model of each measurement in each group [42]. We used the observed daily percent change (DPC) to characterize the trend of improved percentages from baseline (day 0) to the completion of 4-week APA treatment (day 28).

Next, a general linear mixed model was applied to capture the influence on longitudinal pain intensity change. The linear predictors containing treatment group (real APA vs sham APA), total APA pressing time, and average minutes of pressing were used to fit three outcome variables (i.e., worst pain score, average pain score, and current pain score). We also used a polynomial with

Table 2 Descriptive characteristics of pain intensity for between group comparisons

		Baseline Mean (SD)	*P* Value*	End of Intervention Mean (SD)	*P* Value*	Reduction Within Group Mean (SD)‡	Difference of Reduction Between Groups Mean (95% CI)†	*P* Value	Effect Size† (Cohen's D)
Intent-to-treat (ITT) (real, n = 30; sham, n = 31)									
Worst pain	Real	6.90 (1.85)	0.63	3.81 (3.12)	0.004	−3.10 (2.68)	−2.10 (−3.32, −0.88)	0.001	1.20
	Sham	7.13 (1.87)		6.13 (2.93)		−1.00 (2.03)			0.41
Average pain	Real	6.87 (1.82)	0.78	2.85 (2.54)	0.02	−4.02 (2.22)	−1.52 (−2.61, −0.42)	0.01	1.82
	Sham	7.00 (1.82)		4.50 (2.70)		−2.50 (2.06)			1.09
Current pain	Real	4.23 (2.69)	0.50	2.68 (2.69)	0.01	−1.55 (2.14)	−1.45 (−2.64, −0.26)	0.02	0.58
	Sham	4.70 (2.74)		4.60 (3.25)		−0.10 (2.50)			0.03
Per-protocol (PP) (real, n = 25; sham, n = 21)									
Worst pain	Real	6.73 (1.97)	0.90	3.15 (2.84)	0.004	−3.58 (2.61)	−2.02 (−3.52, −0.54)	0.01	1.46
	Sham	6.80 (1.79)		5.65 (2.70)		−1.55 (2.13)			0.50
Average pain	Real	6.77 (1.95)	0.96	2.50 (2.32)	0.01	−4.48 (1.99)	−1.63 (−2.89, −0.37)	0.01	1.99
	Sham	6.80 (1.79)		4.35 (2.30)		−2.85 (2.23)			1.19
Current pain	Real	4.15 (2.92)	0.80	2.38 (2.86)	0.17	−1.77 (2.25)	−1.42 (−2.98, 0.14)	0.07	0.61
	Sham	3.95 (2.44)		3.60 (2.95)		−0.35 (3.00)			0.13

* *P* value is obtained from the mean difference comparison between real APA and sham APA in baseline or end-of-intervention via the *t*-test.

† The effect size is determined by the Cohen's d statistics based on means between baseline and end-of-intervention in real group and sham group using the intent to treat study participants.

‡ Reduction = EOI − baseline.

CI = confidence interval; EOI = end-of-intervention.

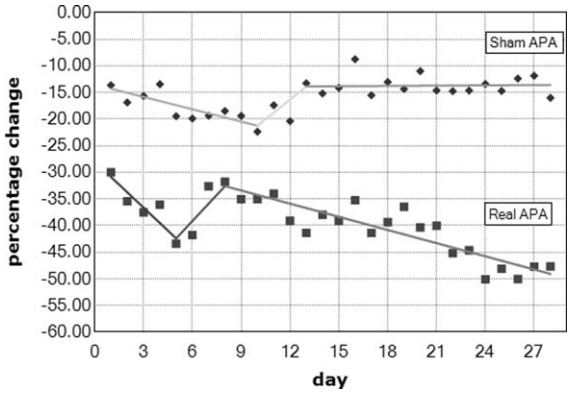

Figure 2 Percentage change of worst pain intensity during the 4-week APA for the real and sham groups.

the maximum degree of three for continuous calendar time. A model selection was applied to detect whether or not a polynomial should remain in the final model. Eventually, the final model for worst pain contained quadratic and cubic time effects; however, only the linear time effect was kept in the final models for average pain and current pain. A covariance matrix with a first-order autoregressive structure was fulfilled to consider temporal correlations of the longitudinal model. SAS software version 9.2.3 (SAS Institute Inc., Cary, NC) was used for descriptive statistics and longitudinal data analysis. The trend analysis was performed by Joinpoint Regression Program version 4.0.4 [43]. Statistical significance was defined by a *P* value of less than 0.05.

Results

Demographic Characteristics

During initial enrollment, 87 participants were screened, and 26 participants were excluded from the study (see Figure 1). In total, 61 participants were randomized into either the real APA group (n = 30) or the sham APA group (n = 31). Figure 1 depicts the process by which subjects were recruited. The demographic characteristics of the 61 participants are presented in Table 1. Their mean age was 63.3 years (SD = 16.70; range 20–90 years), 41 (67.2%) were female, and 51(83.6%) were white. There were no statistically significant demographic characteristics between the real and sham APA groups. In addition, there were no statistically significant differences in pain intensity (including worst pain, average pain, and current pain) at baseline assessment between the real and sham APA groups (see Table 2). The attrition rate was 17% for the real APA group and 32% for the sham APA group. To identify variables (such as age, gender, marital status) associated with dropout, participants who dropped out tended to be older (mean = 73.87, SD = 8.91) compared with those who completed the intervention (mean = 59.89, SD = 17.38). There were no statistically significant differences in gender (*P* value = 0.96) and marital status (*P* value = 0.39) among participants who completed the intervention vs those who dropped out in both groups. For the participants who completed the APA intervention (n = 46) in both groups, 91% of participants (n = 42) believed that they were enrolled in the real APA group. All participants in the study reported that it was not difficult to press the seeds taped on their ears three times/day for 3 minutes/time.

Primary Outcomes of the APA Treatment (Between Group Comparisons)

The primary outcomes for the real and sham APA groups are presented in Table 2 for ITT and PP, respectively. Due to the similar findings (i.e., no statistically significant difference in outcomes between ITT and PP), only findings from ITT are discussed hereafter. For pain intensity at baseline, there was no difference between the two groups, while lower pain scores in three pain intensity measurements at EOI were observed in the real APA group. The greatest mean reduction (i.e., −4.02; SD = 2.22) was recorded in "Average Pain" for the real APA group. The difference of reduction from baseline to EOI between the two groups was statistically significant, where "Worst Pain" for the real APA group decreased more than that of the sham group by −2.10 (*P* value = 0.001).

Change Over Time in Daily Worst Pain Intensity

Figure 2 shows three linear trends of the change in worst pain intensity from the baseline assessment (i.e., before APA at day 0) to the completion of the 4-week APA (i.e., day 28) in both treatment groups. For the real APA group, the observed worst pain mean score decreased 30.0% after the first day of APA treatment, reached the largest decrease (50.08%) at day 24, and eventually settled at a 47.67% reduction at day 28. Two significant joinpoints were found at day 5 and day 8, suggesting that three significant changes occurred in the improvement pattern of worst pain. The greatest improvement shown in Table 3—demonstrated by the daily percentage change (DPC)—was 2.88% (95% CI = 0.90, 4.87; *P* value = 0.0099) per day from day 1 to day 5. This improvement steadily continued from day 8 to day 28 (DPC = 0.82%; 95% CI = 0.62, 1.03; *P* value < 0.0001), which suggests continuous improvement of worst pain in 21 of 28 days after receiving real APA treatment. One slight increase in reported worse pain was observed for day 5 to day 8, but it was not statistically significant (*P* value = 0.3098). For the sham APA group, the worst pain decreased 13.64% on day 1 and significantly decreased to 22.37% through day 10 (DPC = 0.77%, 95% CI = 0.30, 1.25; *P* value = 0.046), which is the first significant joinpoint. While the second joinpoint occurred at day 13, producing two more linear trends, there was no more significant improvement from day 10 to day 28. The percentage change of worst pain

Table 3 Trends in percentage improvement between real APA and sham APA groups

	Real APA					Sham APA				
	Period	DPC	95% CI		*P* Value	Period	DPC	95% CI		*P* Value
Worst pain	1–5	−2.88	−4.87	−0.90	0.0099	1–10	−0.77	−1.25	−0.30	0.0046
	5–8	3.27	−2.88	9.43	0.3098	10–13	2.46	−2.67	7.59	0.3587
	8–28	−0.82	−1.03	−0.62	<0.0001	13–28	0.02	−0.20	0.24	0.8714
Average pain	1–28	−0.40	−0.49	−0.32	<0.0001	1–4	−2.42	−5.03	0.20	0.0831
						4–28	0.03	−0.09	0.14	0.6689
Severity	1–28	−0.65	−0.89	−0.41	<0.0001	1–4	7.83	3.97	19.62	0.2106
						4–10	−6.96	−10.96	−2.97	0.0033
						10–14	8.37	0.64	16.09	0.0487
						14–28	0.36	−0.52	1.24	0.4287

DPC = daily percentage change (%); CI = confidence interval.

in the real APA group was statistically higher than participants in the sham APA group at the completion of the 4-week APA treatment (Table 2).

Change Over Time in Daily Average Pain and Current Pain Intensity

The trajectories of average pain intensity change and current pain intensity change are presented in Figure 3 and Figure 4, respectively. For the real APA group, both average pain and current pain display similar improvement patterns. On the first day of treatment, the mean score for average pain decreased 21.91%, and the mean score for current pain decreased 29.41%. Table 3 demonstrates that worst pain intensity steadily improved throughout the 4-week APA treatment, with a statistically significant DPC of 0.7% (95% CI = 0.58, 0.82; *P* value < 0.0001) for average pain and 0.65% (95% CI = 0.41, 0.89; *P* value < 0.0001) for current pain until the end of the treatment. Therefore, no significant joinpoint was observed for both average and current pain after receiving real APA treatment, which indicates that both average and current pain intensity underwent linear improvement over time. For the sham APA group, only one significant change in average pain was observed at day 4 to produce two linear trends; nonetheless, neither of these trends was statistically significant. Figure 4 demonstrates that the change pattern of current pain intensity for the sham APA group fluctuated, while Table 3 reveals that only one linear trend had a significant pain improvement from day 4 to day 10, with a DPC of 6.96% (95% CI = 2.97, 10.96; *P* value = 0.0033).

Relationship of Seed Pressing Time, Frequency, and Analgesic Use to Pain Intensity Change

Table 4 demonstrates that the total amount of time (in minutes) the APA seeds were pressed per day (mean = 9.28, SD = 10.79 for real APA group; mean = 7.68, SD = 7.30 for sham APA group), the average amount of

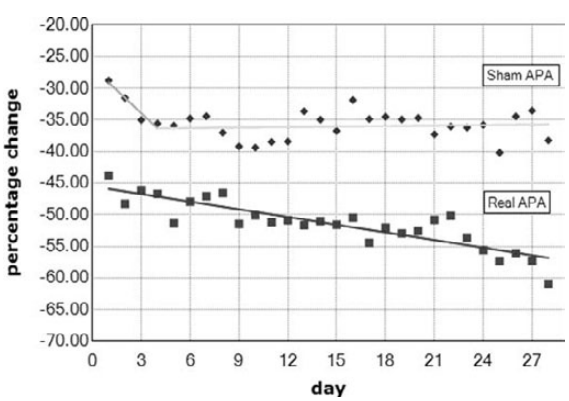

Figure 3 Percentage change of average pain intensity during the 4-week APA for the real and sham groups.

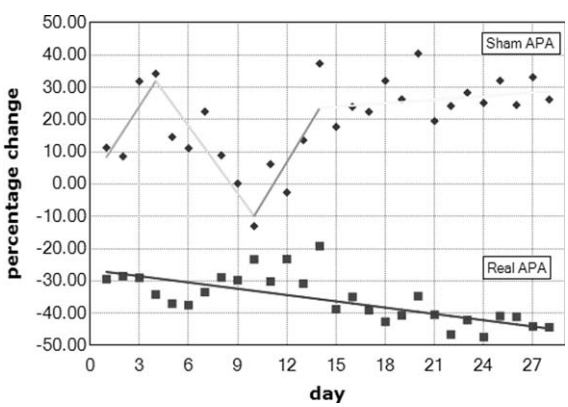

Figure 4 Percentage change of current pain intensity during the 4-week APA for the real and sham groups.

Table 4 The estimated coefficients and standard errors of main effects to pain intensity

	Worst pain		Average pain		Current pain	
	Estimate (SE)	*P* Value	Estimate (SE)	*P* Value	Estimate (SE)	*P* Value
Group	−1.5572 (0.4111)	0.0003	−0.9303 (0.3972)	0.0214	−1.3641 (0.4563)	0.0036
Time	−0.4012 (0.0858)	<0.0001	−0.7212 (0.0702)	<0.0001	−0.0204 (0.0175)	0.2434
$Time^2$	0.0284 (0.0073)	<0.0001	0.0510 (0.0060)	<0.0001		
$Time^3$	−0.0006 (0.0002)	<0.0001	−0.0010 (0.0001)	<0.0001		
Total pressing time	−0.0408 (0.0182)	0.0262	−0.0512 (0.0144)	0.0004	−0.0145 (0.0173)	0.4029
Average minutes per pressing	−0.0517 (0.0229)	0.0243	−0.0648 (0.0181)	0.0003	−0.0577 (0.0217)	0.008
Analgesic use	0.0763 (0.0185)	<0.0001	0.0210 (0.0149)	0.1610	0.0129 (0.0179)	0.4718

SE = standard error.

time (in minutes) the seeds were pressed per day (mean = 2.77, SD = 2.73 for real group; mean = 2.08, SD = 2.46 for sham group), and analgesic use developed a statistically significant association with worst pain intensity, which suggests that each 1-minute increase in pressing the seeds significantly reduced the worst pain score by 0.04 (*P* value = 0.0262). Additionally, there was a 0.05 decrease for average pressing time (*P* value = 0.0243); however, there was a 0.08 increase in the worst pain score from analgesic use (*P* value < 0.0001).

Similarly, each 1-minute increase in total amount of time the seeds were pressed significantly reduced average pain by 0.05 (*P* value = 0.0004). There was a 0.06 reduction in pain for the average pressing time (*P* value = 0.0003), while the change related to analgesic use was not significant (*P* value = 0.1610). For current pain only, the average pressing time significantly reduced current pain by 0.06 (*P* value = 0.008) per 1-minute increase; however, we did not find a statistically significant relationship between total pressing time and analgesic use for current pain intensity. In comparing the treatment groups, the real APA group had a significantly lower pain score by 1.55 (*P* value < 0.0001) for worst pain, 0.93 (*P* value = 0.0214) for average pain, and 1.36 (*P* value = 0.0036) for current pain, when compared with the sham APA group.

Discussion

This is the first study to report the daily pain intensity change trajectory of a 4-week APA protocol to manage CLBP. A 30% reduction of worst pain was recorded after the first day of APA treatment, and pain improvement continued throughout the 4-week APA treatment, culminating in a 44% pain reduction at the completion of the 4-week APA in the real APA group. This magnitude of pain reduction reached the clinically significant level of improvement of 30% for clinical trials of chronic pain therapies [44]. These findings suggest that APA not only is a rapid onset, stable treatment, but also incrementally reduces pain intensity.

Before we further interpret our findings, the following study limitations need to be acknowledged. First, the study did not assess the provider-patient relationship. Therefore, we were not able to differentiate the true effects of APA from the possible psychological effects (i.e., frequency of visits by the auricular therapist or the patient's expectations of APA treatment), which may have introduced additional placebo effects than those controlled by sham acupoints. In a future study, a questionnaire could be used to measure the patient-provider relationship and determine whether or not APA outcomes are subject to placebo effects due to the provider-patient relationship. Second, the dropout rate (32%) was higher in the sham APA group, which limits the comparisons that can be made between the two APA groups. To address this issue, strategies will need to be implemented in any future study to improve participant retention, which could include 1) calling the participants when a treatment session is missed to discern the cause, and 2) providing transportation for participants, especially older ones. Third, physical functioning, which is also a major outcome variable for CLBP, was not included in the daily diary. A future study should include functional status (i.e., Roland-Morris Disability Questionnaire [45] or Oswestry Low Back Pain Disability Index [46]) as part of the outcome measure in the daily diary. Fourth, the therapist delivering the APA treatment was not blinded to the study, so our results embody a certain degree of bias concerning the effect estimate for specific effects. To address this issue, strategies could include deploying a trained therapist who does not know the condition of the participants and follows a standard treatment protocol to administer the APA treatment to a variety of chronic pain patients as well as healthy controls. Finally, a paper-format daily diary was used to collect data. As a result, we are not certain whether or not the participants completed the diary by the end of each day as instructed. A better method of collecting data, such as an Internet- or wireless-based

electronic momentary assessment (EMA) for the daily diaries could be deployed using, for example, smartphones. In addition to enhancing the validity of the pain reports, an EMA could allow participants to more precisely quantify the time per day in which they provide manual pressure to the *Vaccaria* seeds.

Although participants were able to complete the paper-format 28-day daily diary to assess APA practice, pain intensity, and medication use, there may have been recall errors (e.g., overestimated pain intensity) [47,48]. For example, in a study of rheumatology patients (n = 97) who completed 1) up to six momentary ratings of pain per day and 2) end-of-day recall ratings of pain for 28 consecutive days, the end-of-day recall displayed a higher pain intensity than did the daily, mean momentary assessment (i.e., five points higher on a 100-point scale, $P < 0.01$) [49]. In addition, statistical differences were also found in between-person and within-person (i.e., repeated measures) analyses;[49] moreover, the study demonstrated that smartphones can capture daily momentary pain ratings with electronic date-time stamps [49]. The use of these electronic diaries (e-diaries) can also increase and enhance compliance in pain reduction interventions [50,51]. For example, in a study comparing paper vs e-diaries for assessing pain intensity, participants who reported 90% compliance via the paper-format diary actually had only 11% compliance as reported by the e-diaries [48].

The effectiveness of APA for CLBP depends on adherence to the APA treatment protocol of stimulating ear points (i.e., the duration and frequency by which the taped seeds are pressed) to achieve treatment effects, which is supported by the results of our study. None of the participants in our study had heard about APA before they enrolled in our study. Although they were skeptical about APA, they expressed their willingness to try anything to control their low back pain. At the completion of the 4-week APA treatment, we conducted an informal interview with the participants and found that when they did not get relief for their CLBP, they began losing their faith in the APA treatment and tended to not press the seeds. Conversely, participants were motivated after they felt pain relief and pressed the seeds, hoping their CLBP would be cured. However, we are uncertain about the optimal duration and pressure needed to achieve the reported pain relief. A systematic review of acupressure (including both body and auricular points) demonstrates that a standard procedure and treatment protocol, particularly with respect to frequency and time of point stimulation, is missing for acupressure to manage pain [52]. Therefore, a subsequent APA intervention study targeting CLBP will need to address this shortcoming.

An important variable of treatment that was not included in the design of this study was form of stimulation. As a result, we do not know whether or not the taped-on seeds alone without any pressure would be effective in treating CLBP. Moreover, this variable would have an impact on the placebo effect. To address this issue, the inclusion of another control group—one having only tape placed on the real acupoints that would not be pressed by the therapist or participants—would strengthen the study. The addition of this group would allow the assessment of whether or not the form of stimulation has an effect on treatment outcomes.

Adverse effects of APA reported during our CLBP treatment were minimal. For example, some participants (n = 11) reported soreness and tenderness of the ear during the first few days of the treatment. These uncomfortable symptoms disappeared after 3–7 days. Another adverse effect was irritation and sensitization caused by the adhesive tape used during the treatment, which was reported in week 3 by three participants. No serious complications were reported.

The improvement in pain reported by those in the real APA group compared with the improvement by participants of the sham APA group indicates that the effect of APA is point specific. It also indicates that APA may work through different mechanisms than full body acupuncture. In addition, APA may have body regional specificity, which has been supported in a meta-analysis of auricular therapy for pain management [53]. In our study, the selected sham points were not only distinct from the zones of the ear (and the points therein) associated with lower back pain, but also corresponded to body regions in which the participant was pain-free. Because an ear zone system with standardized nomenclature has been established with proven therapeutic effects [14], further studies are needed to differentiate whether or not ear points are point or region specific.

Finally, there was lower analgesic use in the real APA group than there was in the sham APA group; however, there was no statistically significant differences between the two groups. We also found an unexpected finding: analgesic use was related to higher worst pain intensity. Participants who took analgesics regularly had a mean worst pain intensity of 7.74 (SD = 1.79) compared to participants who did not take analgesics (mean = 6.44, SD = 1.71, $P = 0.05$) at the time of study enrollment. This finding presents an opportunity for an intervention such as APA, which appears to reduce worst pain intensity.

Conclusion

In this study, we observed a 30% reduction of worst pain after the first day of APA treatment for CLBP among the participants in the real APA group. Moreover, a continuous improvement of 44% was observed among participants in the real APA group by the end of the 4-week APA treatment. Our findings suggest that APA is an effective, noninvasive treatment that offers a simple way to pain relief. In addition, APA can be used as an adjunct therapy to other forms of pain management and can promote a reduced use of analgesics,

which can minimize potential adverse effects and tolerance. However, further studies of APA are needed to determine the efficacy of auricular therapy for pain. Large-scale RCTs of APA must take into consideration methodological design, including point specification, stimulation, treatment duration, placebo effects, and patient expectation of treatment outcomes. Moreover, given the day-to-day fluctuation in ratings, tighter ecologic assessment of pain scores and other treatment parameters is an important pragmatic aspect of study design.

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