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Self-Administered Acupressure for Chronic Low Back Pain: A Randomized Controlled Pilot Trial

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Abstract

Objective. Chronic low back pain (CLBP) is associated with fatigue, pain, poor sleep, and disability. Acupressure is a low-risk treatment option used to manage symptoms in other groups, but its efficacy, particularly on fatigue and sleep, is unknown in CLBP. This study examined preliminary effects of two types of self-administered acupressure (relaxing and stimulating) on fatigue, pain, sleep, and reported disability. **Methods.** A randomized pilot trial was conducted (N = 67) in which participants were randomized into six weeks of relaxing acupressure, stimulating acupressure, or usual care. Fatigue was measured by the Brief Fatigue Inventory, pain was measured by the Brief Pain Inventory, sleep was measured by the Pittsburgh Sleep Quality Index, and reported disability was measured by the Roland Morris Scale. **Results.** Baseline characteristics were similar across groups. An intent-to-treat analysis using general linear models showed positive improvement in pain in acupressure groups compared with usual care. Pain was reduced by 35–36% in the acupressure groups. Improvement in fatigue was also found in stimulating acupressure compared with usual care. Adverse events were minimal and related to application of too much pressure. **Discussion.** Although this was a small study, acupressure demonstrated promising preliminary support of efficacy for pain and fatigue reduction in this population.

Key Words: Complementary and Alternative Medicine; Nonpharmacological

Introduction

Chronic low back pain (CLBP), back pain that persists for three or more months [1], is the second leading cause of disability in the United States [2, 3] and is a main reason for physician visits, hospitalization, or seeking other health care services [4]. In addition to persistent pain, a high proportion of individuals with CLBP report both sleep disturbances [5–7] and depression [8]. Moreover, these symptoms are associated with higher levels of fatigue [6, 9]. The burden of CLBP on health care costs and individual quality of life is high; however, increasing health care costs for treatment have not translated into greater improvements in health or function [10]. Pharmacologic treatments are common, are associated with side effects, and, in the case of opioid prescription, increase the risk of medication abuse and addiction [11]. Nonpharmacologic interventions may be particularly important in helping to reduce symptom burden and disability associated with CLBP, especially those that are low cost and easy to administer.

Acupressure is a Traditional Chinese Medicine (TCM) technique that involves placing physical pressure on

specific acupoints using a finger, thumb, or device. Systematic reviews on acupressure have provided support for its significant effects in a variety of groups for chronic symptoms, such as pain and sleep disturbance [12–14]. Acupressure studies in CLBP samples have primarily investigated pain and disability outcomes and are relatively limited. Two studies of therapist-applied acupressure vs physical therapy, each provided six times over a one-month period, provided support for significant improvements on pain and disability post-treatment and at six-month follow-up [15, 16]. Studies of self-administered acupressure in CLBP have most commonly used auricular stimulation in which participants stimulate a small seed taped to the outer ear. A recent meta-analysis of auricular acupressure showed effects on pain, but there were no effects on disability scores [17]; participants also reported several adverse events that could affect long-term treatment adoption. No study could be found that has examined the effects of self-administered acupressure on symptoms of fatigue and sleep quality in CLBP despite their prevalence and impact on daily function.

In previous studies, our group has examined two types of self-administered acupressure treatments—relaxing and stimulating—applied to various points on the body. Both relaxing and stimulating acupressure treatments have been shown to reduce fatigue in a large cohort of breast cancer survivors, and relaxing acupressure had the added benefit of improving sleep quality [18]. In a study assessing the effects of relaxing acupressure on pain and physical function in older adults with knee osteoarthritis, we found that acupressure was superior to usual care, although a sham acupressure arm showed similar but lesser effects [19]. The specific aims of this study were to examine the efficacy of relaxing and stimulating self-administered acupressure treatments compared with a usual care condition on CLBP symptoms (fatigue, pain, sleep quality) and reported disability. We were also interested in determining participant tolerability and adverse events. Based on our previous studies in other pain samples, we hypothesized that the acupressure treatments would have positive effects on fatigue, pain, and sleep quality compared with usual care and that relaxing acupressure would likely show the greatest improvements. We also hypothesized that both relaxing and stimulating acupressure would be more effective in improving reported disability than usual care.

Methods

Design

This was a three-group, six-week randomized controlled pilot trial comparing relaxing acupressure, stimulating acupressure, and usual care for individuals with nonspecific chronic low back pain. Participants were allocated to the interventions using a 1:1:1 ratio by study staff. A statistical consultant generated a randomization schedule in randomized blocks of six and nine using SAS statistical software. All study staff were blinded to the study hypotheses, and neither acupressure educators nor participants in the acupressure groups were aware of which acupressure was relaxing or stimulating. Participants were instructed to self-administer acupressure daily. The study protocol was approved by the University of Michigan Medical School Institutional Review Board.

Participants

Participants living in or around Southeastern Michigan were recruited from various sources: flyers posted in Michigan Medicine Clinics and the surrounding community, advertisements in local newspapers and newsletters, an online university research participant recruitment website, and electronic medical records. For most recruitment methods, participants called or e-mailed to indicate their potential interest. From electronic medical records, an informational letter was sent to potentially eligible individuals with one or more ICD-9 codes indicating nonspecific low back pain that included an opt-out postcard. If no postcard was received, a call was made to ask individuals if they would be interested in participating. All participants were screened by phone for preliminary eligibility and, if eligible, were scheduled for an in-person visit.

Participants were eligible if they were aged 18 years or older, had nonspecific low back pain (either by self-report or determined by medical record ICD-9 codes 724.2, 724.5, and 846.0–846.9), had low back pain that had persisted for at least three months, had a minimum score of 4 out of 10 on the Pain Bothersome Scale [20], reported a minimum of 3 out of 10 fatigue severity, were ambulatory with or without an assistive device, were able to adequately operate the accelerometer (Actiwatch-S) used to collect study data, were on a stable medication regimen for the previous two months, had a report of a physician's visit during the previous 24 months, and were English-speaking. Individuals were not eligible if they were medically unstable, were currently pregnant, had radiculopathy or report of low back pain radiating below the knee, reported back surgery within the preceding 12 months, were participating in active litigation or compensation claims related to their back pain, had conditions that might confound treatment effects or interpretation of results (e.g., rheumatoid arthritis, lupus), received acupuncture or acupressure within the preceding 12 months, reported sleep apnea, were shift workers, or had other nontraditional sleep schedules.

Procedures

Individuals were scheduled for an in-person visit at a Michigan Medicine research clinic in which written informed consent was obtained and baseline measures were collected. Participants received instruction on the seven-day home monitoring period in which an accelerometer, enhanced with a feature to collect numerical responses (Actiwatch-Score), was utilized to collect baseline physical activity and reports of pain and fatigue in

real time (ecological momentary assessment). After the home monitoring period, participants mailed back the accelerometer and other study materials in a postage-paid envelope. If participants complied with the Actiwatch protocol and entered at least 80% of the requested symptom reports, they were randomized into one of three groups: relaxing acupressure, stimulating acupressure, or usual care. Participants randomized into one of the acupressure groups were scheduled for an in-person acupressure training visit at the clinic followed by weekly phone calls. Participants in the usual care group only received six weeks of phone calls. All participants were scheduled for a post-test clinic visit to occur after the treatment period ended. The seven-day home monitoring visit was repeated at that time. After participants in the usual care group returned their Actiwatch and log, they were offered the acupressure materials from both the relaxing and stimulating treatments, which consisted of a link to a treatment-specific demonstration video and paper copies of instruction.

Interventions

Participants randomized to usual care were told to continue whatever treatments they were receiving from their care providers for their back pain and fatigue. Participants in the acupressure groups were taught to self-administer acupressure by one of three trained acupressure educators. Pressure was applied to each acupoint in a circular motion for three minutes per point, and pressure could be applied using a wooden acupressure aid provided in the study (acu-ki; www.bodytools.com), a pencil tip eraser, or fingertip. Once the participant selected a method to apply pressure, they were asked to use that same method for the study duration.

Acupoints in both relaxing and stimulating acupressure were chosen by consensus of four acupressure practitioners and were based on our team's previous studies [18, 19, 21]. The relaxing acupressure is thought to be effective in reducing fatigue because the acupoints are used to reduce insomnia. In relaxing acupressure, there were five acupoints, with four of the acupoints performed on both the left and right sides of the body (total of nine points). The acupoints were *Yin tang*, *Anmian*, Heart 7 (HT7), Spleen 6 (SP6), and Liver 3 (LIV3) (Appendix). Stimulating acupressure is thought to have effects on fatigue reduction in particular. Stimulating acupressure consisted of six acupoints, with four of the acupoints performed on both the left and the right sides of the body (total of 10 points). The acupoints were *Du 20, Ren 6* (Ren 6), Large Intestine 4 (LI4), Stomach 36 (ST36), Spleen 6 (SP6), and Kidney 3 (K3). Based on the timing to administer, participants would need to spend between 27 and 30 minutes daily applying acupressure.

Demographics and Clinical Variables

Demographics included age, sex, race, ethnicity, marital status, and employment. Clinical variables included medications used, body mass index, anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) [22], and total number of pain sites using the Michigan Body Map [23]. To characterize objective physical function, the Six Minute Walk test was used, in which individuals were asked to walk a standard course at their usual pace for six minutes and the distance was recorded in meters [24].

Outcomes

Outcomes were assessed at baseline and after the treatment period during in-person visits. Fatigue was measured by the Brief Fatigue Inventory (BFI) [25], which has been validated in samples with chronic pain [26]. Respondents rate their fatigue on a scale of 0 = "no fatigue" to 10 = "fatigue as bad as you can imagine" related to general severity of fatigue and its interference in daily life. This scale is typically scored by averaging nine of the 10 items. Internal reliability at each study assessment was high (Cronbach's alpha = 0.96). Although a clinically significant improvement on this scale has not been established, we have operationalized a two-point or 30% decrease in fatigue to be significant as these are the cutoffs for 0–10 pain scales [27].

Pain was measured by the Brief Pain Inventory (BPI), which has been validated in chronic pain samples [28, 29]. A total score reflecting pain severity and pain interference is calculated. The internal reliability of the scale at each study assessment was high (Cronbach's alpha = 0.91 and 0.95). A clinically significant improvement in pain was considered a two-point or 30% decrease [27].

Sleep disturbance was measured by the Pittsburgh Sleep Quality Index [30]. This measure is a self-report measure of sleep disturbance measuring seven components: sleep quality, sleep latency, duration, efficiency, disturbances, use of sleeping medications, and daily dysfunction within the previous month. Measures of each component are transformed to a 0–3 scale and then summed. A score of ≥ 5 indicates significant sleep disturbance in adults [30]. The reliability was adequate at baseline and the post-test study assessment (Cronbach's alpha = 0.70 and 0.74).

Reported disability was measured by the Roland Morris Disability Questionnaire [31], a 24-item scale that is commonly used with back pain samples and has good internal consistency, discriminative validity, and sensitivity to change [31–33]. A sum of items is used to generate the overall score. The internal reliability of this scale was good (Cronbach's alpha = 0.83 and 0.85). A 30% decrease is considered a clinically important improvement in back pain samples [34].

Home Monitoring Period

Participants were instructed to wear the Actiwatch-Score on their nondominant wrist for seven days and to input ratings of pain and fatigue severity into the device five times per day at prespecified times following an audible

prompt, as well as recording ratings in a logbook. They also reported wake and bed times in the logbook to assist in data processing. A seven-day monitoring period was selected because it is considered an acceptable amount of time to obtain reliable and valid physical activity data in adults [35, 36]. Participants were asked to wear the device continuously except for times when the device could become wet (e.g., showering or swimming). At the end of the home monitoring period, participants were compensated $20 upon receipt of materials. Participants who supplied adequate data from the home monitoring period were randomized into one of the three groups.

Intervention Fidelity

Strategies to ensure intervention fidelity included standardized training of acupressure educators, proper enactment of the intervention procedures, and methods to track adherence with the intervention procedures. Acupressure educators were trained by one of the study's co-investigators (RH), a nationally certified and experienced acupuncturist. Acupressure educators practiced with the acupuncturist to deliver the training according to the standardized protocol and were observed providing the training periodically to ensure that correct instruction was given. The acupuncturist was also consulted if participants had questions about their acupressure practice. Participants were trained and evaluated at the end of the initial training for their ability to accurately locate and stimulate their acupoints. The acupressure educator asked participants to identify each of their acupoints and to stimulate one point on the educator. The number of acupoints correctly located was recorded on a case report form, as was the adequacy of stimulating the acupoints (Appendix). Participants were corrected and asked to relocate acupoints as needed. To support enactment of the acupressure, participants were provided with an intervention arm–specific weblink to videos created by the study team that demonstrated either relaxing or stimulating acupressure. Participants also received a handout with written instructions (Appendix). They were provided with an acu-ki device if they chose to apply pressure with that aid and a timer to track the three minutes of applied pressure at each point. To track adherence, participants were asked to record completion of their acupressure treatments in a daily log. Participants were called weekly to track adherence and were asked about any adverse effects or complications in practicing the acupressure as taught. Adherence to acupressure daily (indicated by yes or no) was tallied across the reporting period and divided by the total number of sessions possible in the study (42; i.e., six weeks × seven days) to determine percent adherence. Weekly calls were also done in the usual care group, in which changes in health status were queried. This was done to maintain contact with both groups equally so that the acupressure groups would not benefit from increased contact.

Statistical Plan

Based on our power analysis for a general linear model of three groups using data from a sample with chronic fatigue due to cancer [21], we needed 56 total participants to complete the protocol to detect a medium effect of $d = 0.5$ with 80% power in fatigue reduction. Demographic and clinical variables were compared between those who were screened and were either eligible or not eligible using t tests for continuous variables and chi-square or Fisher's exact tests for categorical variables. Descriptive analyses were performed on baseline values. We performed a data analysis using data from all completers. We investigated the difference in each outcome variable at six weeks among treatment groups using separate general linear models adjusting for the baseline value of that variable, age, and sex. We then used an intent-to-treat approach that involved multiple imputation and sensitivity analyses. We analyzed patterns of missing data that showed that data were largely missing due to non-completers in the sample (N = 12). We then utilized a recommended approach to examine the effect of potentially influential variables on data that are missing not-at-random, in which missing values are imputed based on pattern-mixture modeling [37]. Five imputation models were performed including all outcome variables, the baseline value of each outcome measure, and all other predictors. All outcome variables were included in these imputation models as auxiliary variables because of their significant and moderate intercorrelations ($\geq$0.4). Because these models were largely similar, we are presenting the recommended fully conditional specified model [38], which allowed each variable to be imputed using its own conditional distribution and where treatment arm is in the multiple imputation model. The only variable with missing data at baseline, Pittsburgh Sleep Quality, was imputed per its own treatment group distribution. The primary analysis is presented using this intent-to-treat approach. We undertook a subgroup analysis of the acupressure groups to determine if percent adherence to acupressure affected changes in outcomes. No differences were found based on adherence to acupressure; therefore, our final models are presented adjusting for our original covariates of age, sex, and baseline value of the outcome variable. The imputation analysis was performed using SAS 9.4 (SAS Institute, Cary, NC, USA), MI, and MIANALYZE. Given that this was a pilot study examining preliminary effects, alpha levels were not adjusted for multiple comparisons. Thus, a two-sided P value <0.05 was considered significant.

Results

Participant Flow and Characteristics of the Sample

The participant flow through the study is shown in Figure 1. From all methods of recruitment, 456 participants were screened by phone, and 93% of those screened were interested in participating. People who

were screened but did not meet the inclusion criteria most commonly reported sleep apnea, radiculopathy, or insignificant symptoms (pain or fatigue). From 128 people interested and eligible, 101 came in for the in-person visit and 34 people were ineligible. Those who were eligible (N = 67) did not significantly differ from those who were ineligible (N = 34) by age ($P = 0.82$), race ($P = 0.19$), sex ($P = 0.19$), depressive symptoms ($P = 0.65$), anxiety ($P = 0.06$), pain ($P = 0.24$), or fatigue ($P = 0.31$).

Baseline sample characteristics (N = 67) are shown in Table 1. Overall, the sample was predominantly female and middle-aged (50.1 years, range = 21–86 years), and 28% were nonwhite. The mean body mass index was overweight (29.7), with anxiety and depression scores ranging from normal to mild severity [22]. Approximately 10% of participants reported taking opioids to control their pain, and the neck, shoulders, and hips were other common sites where participants reported pain. There were no significant differences between groups.

Participants had moderate fatigue and pain. Sleep was generally poor, with 85% of the sample having a score of >5, indicating significant sleep disturbance. Reported mean disability on the Roland Morris Scale (8.7 out of 24 points) was better in comparison other chronic back pain samples [33].

Twelve participants did not complete the study. Of these, 58% dropped out before receiving the allocated interventions. Six of those who dropped out were in the relaxing group, and one was in the stimulating group. Of the remaining five participants, four reported wanting to discontinue the stimulating acupressure intervention because they changed their mind, felt the acupressure was too painful, or wanted a different treatment than what was offered. The 12 participants who dropped out were significantly younger than those who completed (mean ± SD = 42 ± 13.4 vs 51.8 ± 12.9 years, $P = 0.02$) and reported higher levels of depressive symptoms and anxiety (7.7 ± 3.1 vs 5.1 ± 3.5, $P = 0.03$; 9.1 ± 4.0 vs 6.1 ± 3.2, respectively, $P = 0.01$).

Primary Analysis

Table 2 shows the intent-to-treat analysis results of each outcome by group using general linear models. Unadjusted means with imputed values for outcome variables by group at baseline and six weeks are depicted in Figure 2. Controlling for age and sex, only the stimulating acupressure had an effect on fatigue reduction compared with usual care. In the stimulating acupressure group, mean fatigue decreased from 4.3 on the BFI at baseline to 3.2 at six weeks (Figure 2), representing a 26% reduction. Both acupressure arms had reduced pain at six weeks compared with usual care. On average, pain was reduced by 35–36% from baseline for the sample for the relaxing and stimulating groups, respectively (4.3 to 2.9 on the BFI for relaxing and 4.5 to 2.9 for stimulating) (Figure 2). No differences were found in sleep quality or reported disability in the acupressure or usual care groups.

Adherence to Acupressure

All participants in the acupressure treatment groups who underwent the training visit to receive instruction for acupressure had adherence log data. Participants who performed acupressure were 85% adherent on average. Participants in the relaxing acupressure group had higher adherence than participants in stimulating acupressure (91% vs 78%). From weeks 1 to 6, adherence declined from 96% to 87% in the relaxing acupressure group, and adherence declined from 85% to 75% in the stimulating group.

Adverse Events

There were four mild adverse events related to the acupressure treatments. All involved applying too much pressure to acupoints. One person experienced bruising, one developed a skin break on the forehead, one experienced a muscle spasm after applying pressure to the arch of the foot, and one person experienced a headache after applying pressure to the forehead. All of the participants were using the acu-ki when the event happened and were advised to modify their procedure for applying pressure by using a finger, thumb, or pencil eraser. The adverse effects dissipated quickly, and all participants completed the six weeks of treatment.

Discussion

In this study, we found that only the stimulating acupressure group had significant fatigue reductions at six weeks in comparison to the other groups, but this did not reach the level of clinical significance. Both relaxing and stimulating acupressure treatments had a positive impact on pain that was modest but higher than what is considered clinically significant (>30% reduction). No differences were seen in the other outcomes measured, sleep quality and reported disability at six weeks; however, participants were largely adherent to completing the acupressure and had low adverse events.

Our study contributes to the body of knowledge on acupressure in chronic low back pain in a few important ways. This is the first study to our knowledge that has investigated self-administered acupressure applied on the body for people with chronic low back pain to reduce fatigue and pain. Previous studies of acupressure for chronic low back pain have investigated either therapist-applied acupressure or self-administered auricular acupressure and have not investigated effects on fatigue. Although both of these types of acupressure had effects on pain similar to our study [15–17], the therapist-delivered and auricular acupressure treatments have

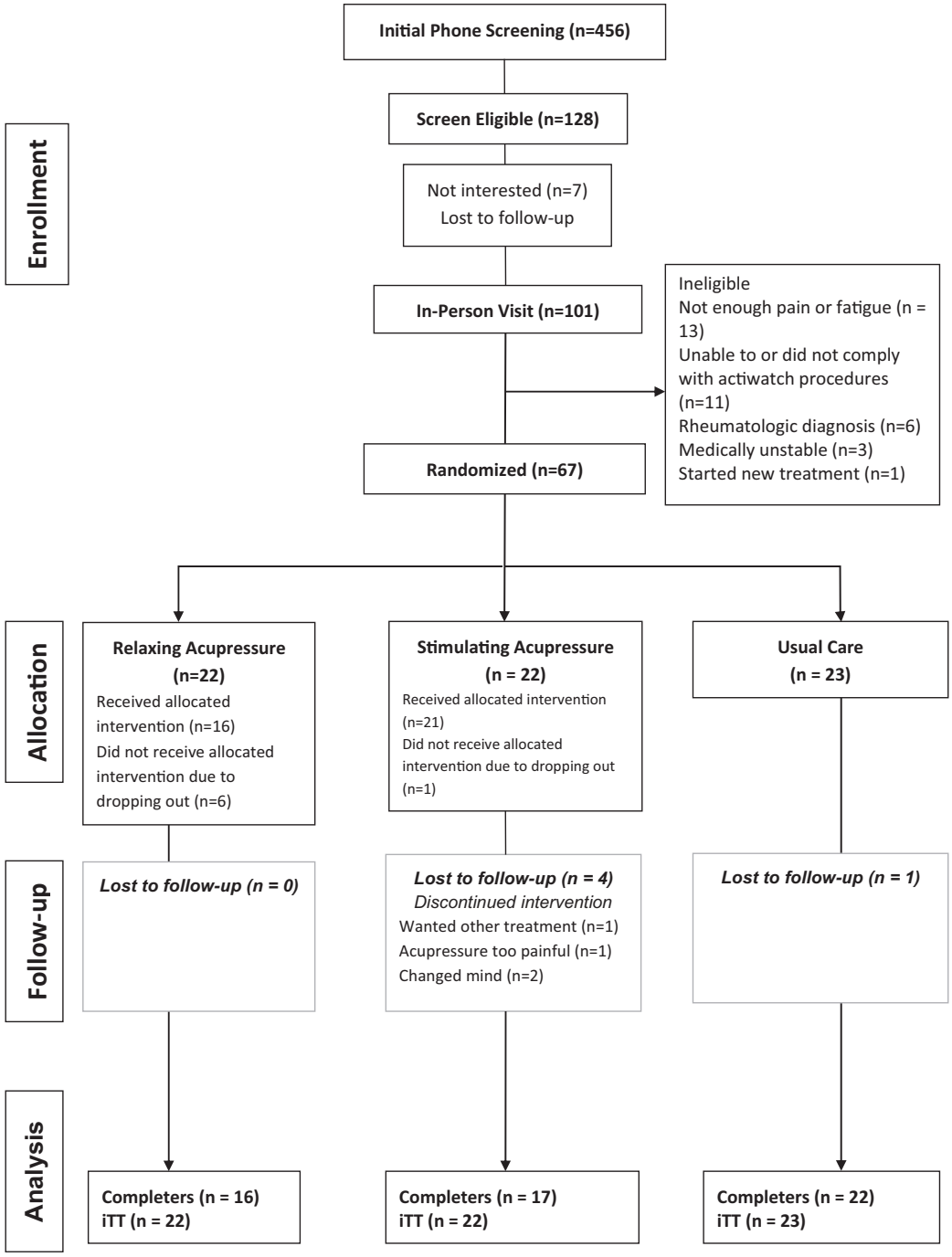

Figure 1. Participant flowchart

potential barriers that could prevent widespread adoption, requiring time and resources to administer and travel for participants. The auricular acupressure also has some adverse events, such as itching, burning, irritation to the outer ear, and sleep disturbances, due to the seed taped on the outer ear, that may preclude long-term adherence. The acupressure approach used in our study requires minimal resources and had a high rate of adherence, which support its acceptability within the sample. Although there were some minor adverse events with the acupoint stimulation, these mainly related to the use of the acu-ki device, which dissipated once they adapted their application technique. A second contribution to the literature is that this study provides some evidence to suggest that stimulating acupressure improved fatigue compared with usual care, which is important given the effects of fatigue on back pain and daily function. Fatigue and sleep quality have demonstrated clinically significant improvement using self-administered acupressure in breast cancer survivors [18, 21]. In addition, a recent meta-analysis on sleep quality showed that acupressure improved sleep on the Pittsburgh Sleep

Table 1. Baseline characteristics of overall sample and by treatment group

Variable	Overall Sample (N = 67)	Relaxing Acupressure (N = 22)	Stimulating Acupressure (N = 22)	Usual Care (N = 23)	*P* Value
Age, y	50.0 (13.5) 21–86	51.1 (13.6)	48.6 (13.8)	50.3 (13.6)	0.83
Sex (female), No. (%)	42 (62.7)	15 (68.2)	13 (59.1)	14 (60.9)	0.80
Race (white), No. (%)	48 (71.6)	16 (72.7)	17 (77.3)	15 (65.2)	0.66
Clinical characteristics					
Uses opioids, No. (%)	7 (10.4)	2 (9.1)	2 (9.1)	3 (13.3)	0.89
Uses prescribed NSAIDs, No. (%)	5 (7.5)	0 (0)	2 (9.1)	3 (13.0)	0.11
Body mass index	29.7 (7.6)	30.8 (7.5)	28.2 (7.6)	30.2 (7.8)	0.52
Total No. of pain sites (body map)	6.0 (4.6)	6.5 (5.1)	5.0 (4.6)	6.6 (4.3)	0.42
Depression (HADS)	5.6 (3.7)	6.2 (4.1)	6.0 (3.5)	4.6 (3.4)	0.27
Anxiety (HADS)	6.6 (3.5)	7.2 (3.8)	7.2 (3.2)	5.6 (3.4)	0.19
Six-minute walk, m	374.7 (63.5)	377.3 (66.0)	350.5 (60.4)	395.4 (58.3)	0.06
Objective physical activity, activity counts/min	367.74 (117.78)	347.74 (94.94)	413.89 (132.2)	337.27 (110.67)	0.08
Fatigue (BFI)	4.2 (2.4)	3.8 (2.9)	4.3 (1.9)	4.4 (2.3)	0.72
Pain (BPI)	4.4 (1.9)	4.3 (2.0)	4.5 (1.8)	4.4 (1.9)	0.95
Reported disability (RMDQ)	8.7 (4.8)	9.1 (5.1)	10.0 (5.2)	7.1 (3.9)	0.12
Sleep quality (PSQI)	8.5 (3.6)	9.3 (4.0)	7.6 (2.8)	8.5 (3.8)	0.29

For objective physical activity, relaxing acupressure, stimulating acupressure, and usual care: N = 19, N = 21, N = 18, respectively. For continuous variables, mean and standard deviation are presented.

BFI = Brief Fatigue Inventory; BPI = Brief Pain Inventory; HADS = Hospital Anxiety and Depression Scale; NSAID = nonsteroidal anti-inflammatory drugs; PSQI = Pittsburgh Sleep Quality Index; RMDQ = Roland Morris Disability Questionnaire.

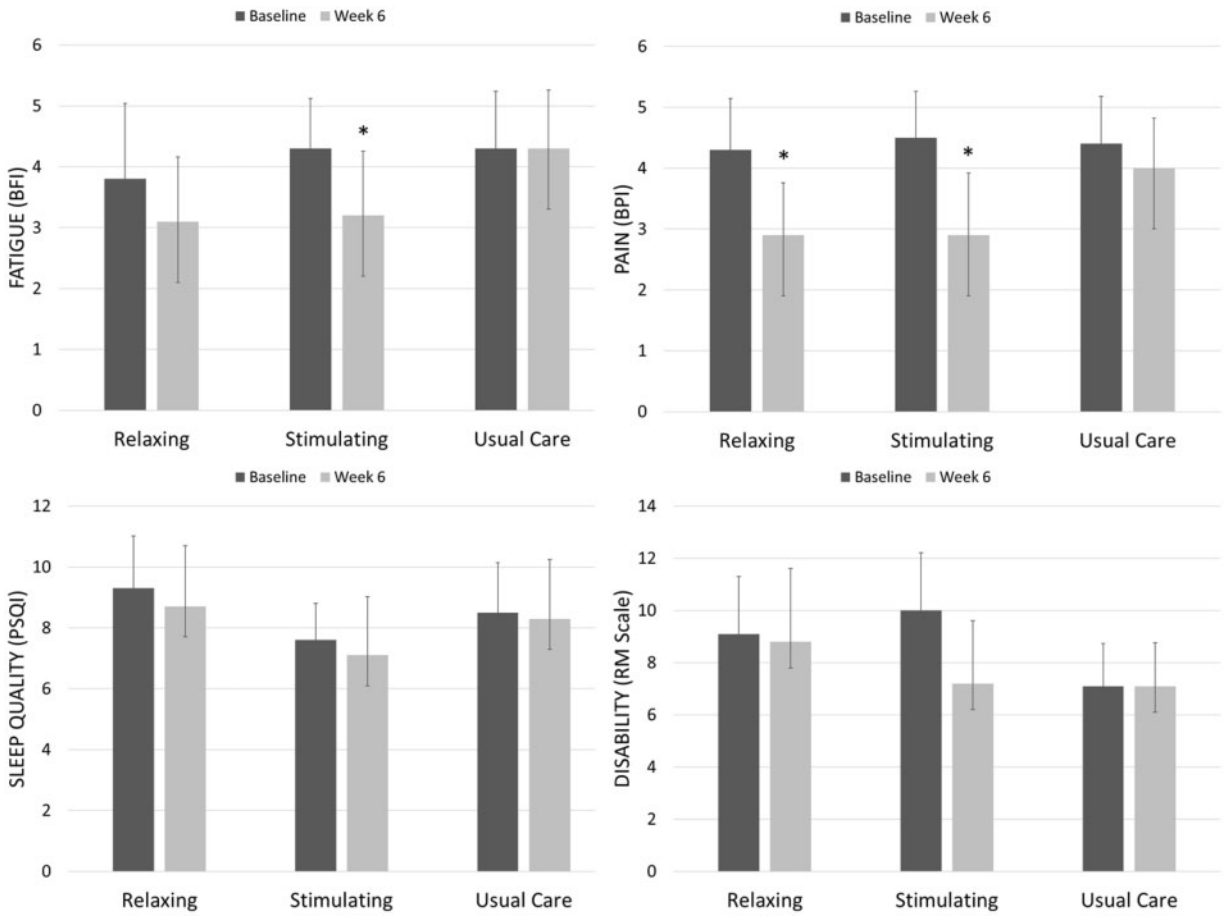

Figure 2. Change in outcomes from baseline to six weeks by group (means and confidence intervals).
Note. Asterisks indicate significant change in acupressure groups compared to usual care group.

Table 2. Effects by acupressure group in the intent-to-treat model

	Variable	B	95% Confidence Limits		*P* Value
Fatigue	Relaxing	−0.97	−2.04	0.10	0.0735
	Stimulating	−1.18	−2.26	−0.10	0.0330*
	Male	−0.71	−1.58	0.17	0.1119
	Baseline fatigue	0.58	0.40	0.77	0.0001*
	Age	−0.02	−0.05	0.02	0.3279
Pain	Relaxing	−1.10	−1.83	2.20	0.0156*
	Stimulating	−1.14	−2.10	−0.18	0.0198*
	Male	−0.37	−1.17	0.43	0.3610
	Baseline pain	0.74	0.54	0.93	0.0001*
	Age	0.02	−0.02	0.05	0.3370
Sleep quality	Relaxing	−0.26	−2.41	1.88	0.8094
	Stimulating	−0.53	−2.79	1.74	0.6457
	Male	−0.65	−2.41	1.10	0.4639
	Baseline sleep quality	0.82	−0.55	1.08	0.0001*
	Age	0.02	−0.05	0.08	0.5577
	Relaxing	0.41	−1.99	2.81	0.7377
Disability	Stimulating	−1.83	−4.21	0.55	0.1313
	Male	0.57	−1.53	2.68	0.5916
	Baseline disability	0.75	0.53	0.98	0.0001*
	Age	0.01	−0.08	0.11	0.7847

Comparisons were made against the usual care group and females. Astericks denote significance of $P < .05$.

Quality Index by 13–19% in various groups [14]. Results in this CLBP sample, using the same self-administered acupressure treatment protocols as some prior studies [18, 21], did not yield the same effects on sleep. The lack of positive findings on these outcomes may be due to the possibility that this study was underpowered to detect these effects in CLBP.

No effects in reported disability were found in this sample, which is similar to other studies of self-administered acupressure in CLBP [17]. Disability in CLBP was improved in a study in which acupressure was provided by a trained therapist and compared with physical therapy [16]; however, several factors may have contributed to the positive effect in that study, such as therapist attention, significant baseline disability on the Roland Morris Scale in almost half of participants, and a lack of intention-to-treat analyses to account for the 16% dropout, which may have inflated effects.

A limiting factor in comparing the findings of the current study with others using CLBP samples is the differences in dose, mode of delivery (self-administered or not), and acupressure protocols. For instance, the optimal dose of self-administered acupressure is not known and may vary by clinical group and outcome studied. In samples of breast cancer survivors, decreases in fatigue tended to taper after six weeks of daily acupressure [18, 21], whereas in a sample of older adults with knee osteoarthritis who were told to practice acupressure five days a week, improvements in pain and disability continued over an eight-week period. Future studies with clearly published protocols that can be replicated in larger studies would advance the understanding of effects of self-administered acupressure in CLBP.

Another factor affecting the comparison of acupressure findings with others is the choice of control group. Sham acupressure conditions have been used as a control in many studies, although the vast majority have not been with chronic pain samples, and acupressure was typically administered by a trained acupuncturist or research team member. These sham conditions, such as providing stimulation to nonacupoints, often produce positive effects but are typically not superior to the true acupressure treatment [39]. Further difficulty in disentangling the effects of sham from acupressure or acupuncture studies arise from bias from the difficulty of adequately blinding participants or an expectation that the treatment will help, contributing to a placebo effect [40]. Sham conditions also have the potential not to be inert. For example, a sham condition showed a dose–response effect on pain in a sample with irritable bowel syndrome [41]. The placebo effect cannot be discounted as a possible mechanism for acupressure. As it is inexpensive and safe, it may have clinical utility regardless of its mechanism of action. Although the current study employed a usual care, no-treatment group as the control condition, it was not possible to blind these participants, and they would have no expectation of improvement from participating in the study. Almost no change was seen in outcomes from the control group over the six-week period. Although this type of control group would likely increase treatment effects from acupressure by comparison, it is important to note that this group may be more generalizable because CLBP is very common and many people do not seek treatment.

Study limitations should be noted. We initially intended to use an objective measure of sleep efficiency (using our Actiwatch device) as a study outcome, but difficulties in

obtaining follow-up data required substitution of this measure with our self-report measure, the Pittsburgh Sleep Quality Index. Although the study sample size was based on a power analysis, the estimate was based on a sample with chronic fatigue due to cancer and not CLBP. A larger study is needed to detect effects between the two types of acupressure tested in this study. As with all studies in which participants know they are receiving a treatment intended to impact outcomes, there is a potential for response bias. We did not adjust the alpha level for the two co-primary comparisons vs the control group in this study. The results are only generalizable to participants with CLBP who are similar characteristically to this sample. Participants had moderate levels of pain and fatigue and a relatively low level of reported disability (score of 8) relative to reports in other chronic back pain populations, which have ranged from 12.1 to 14.2 [33]. Despite the low reported disability, it is important to note that the average six-minute walk (374.7 meters) was considerably lower than healthy cohorts of similar or older age, which range from 571 to 659 meters [42, 43]. Future studies may need to include objective physical function outcomes to better understand these discrepancies. Because most attrition occurred before initiating study treatment, future studies may be strengthened by providing a run-in period to screen out individuals not willing to participate in the protocol. Despite limitations, participants generally adhered to study procedures, and there were only a small number of adverse events related to applying too much pressure, which were rectified easily with education and altering strategies.

Conclusions

The acupressure interventions had positive preliminary effects on symptoms, and the protocol was feasible and well tolerated by the sample with CLBP. Further studies are needed to determine if self-administered acupressure is effective in reducing fatigue and pain in larger samples of people with CLBP.

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