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Research Article

Effectiveness of Manual and Electrical Acupuncture for Chronic Non-specific Low Back Pain: A Randomized Controlled Trial

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ABSTRACT

Background: Low back pain is a common condition that can be effectively treated by acupuncture. However, several treatment point prescriptions and further electrical needle stimulation (i.e., local acupoints, distal acupoints, and sensitized acupoints) may be used. There is an implicit yet unexplored assumption about the evidence on manual and electrical stimulation techniques.
Objective: The present study aims to identify effectiveness of electroacupuncture (EA) and manual acupuncture (MA) on pain and disability in patients with chronic nonspecific low back.
Methods: This study is a randomized controlled clinical trial. Sixty-six patients between 20 and 60 years of age with non-specific chronic low back pain experiencing low back pain lasting for at least the previous three months and ≥3 points on a 10 numerical analogic scale. Patients diagnosed with chronic LBP were assigned to receive either 12 sessions of MA or EA. The primary outcomes measurements were pain intensity on Numeric Rating Scale and disability by Roland Morris Disability Questionnaire.
Results: The participants reported improvements post-treatment to pain intensity and disability respectively; however, no differences between groups were observed. Regarding the secondary outcomes, we observed a between-group difference only for kinesiophobia in favor of the manual acupuncture group (difference = −4.1 points, 95% CI = −7.0 to −1.1). The results were maintained after 3 months of follow-up.
Conclusion: The study provides evidence that EA is not superior to MA treatment. Both therapies had similar efficacy in reducing pain and disability for chronic nonspecific low back pain.

1. Introduction

Chronic nonspecific low back pain (LBP) is a common health problem that is considered a multifactorial disorder [1]. The average of lifetime prevalence of LBP is 39% in adults [2], and is one of largest contributors to disability. The variable accessibility to conventional treatments, patients with LBP have increasingly been using alternative medicine to relieve of the symptom [3,4]. According to recent systematic review [5], upon nonpharmacologic treatment options for low back pain, included exercise, yoga, massage, acupuncture showed decrease of pain intensity more than sham acupuncture after intervention.

Manual Acupuncture (MA) is one of the main treatment modalities of Traditional Chinese Medicine (TCM) [6], that is mostly used for a range of painful and other conditions. On physiological effects, it is known to activate the endogenous pain control systems is defined as the needling of specific points of the body [7]. The technique inhibits the dorsal horn, which can activate or inhibit certain points of the body that stimulate the release of opioids such as serotonin and catecholamine [7,8]. These neurotransmitters produce various effects, such as analgesics, muscle-relaxing, anti-inflammatory, and antidepressant effects [3,9].

Electroacupuncture (EA) is an application of acupuncture combined with electric current used to strengthen the effects [9]. EA could improve the electrical stimulus of certain physiological reactions to obtain a faster analgesic and anaesthetics than traditional manual acupuncture physiological reactions or other produce different might obtain an anesthetic, the low frequencies usually

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are indicated when using EA in patients with LBP [10]. Furthermore, the advantages of a standardized quantity and quality of stimulation, which is achieved by controlling the input current range and frequency, this method can be efficient for pain in general [11].

Despite of evidence supports the effectiveness of several non-pharmacological therapies for low back pain and showed benefits of MA or EA, there is a limited evidence for the these effects, generally were seen for short-term pain (often immediately after intervention), low quality of studies [12-14], and literature when to compared two technics, most studies showed these techniques are applied together, and little compared in isolation.

To our knowledge, there are no previous trials that have studied the effect of a treatment modality that combines MA and EA in patients with LBP. The purpose of study was to examine whether EA is more effective in reducing pain and disability than MA in people with chronic LBP. The hypothesis is that patients receiving electroacupuncture would have better analgesic action and more time without pain and recovery disability than patients who received only acupuncture.

2. Materials and methods

2.1. Study design

This single-blind, randomized, controlled trial was conducted at the Physical Therapy, Speech and Occupational Therapy Department, School of Medicine, University of Sao Paulo, Sao Paulo, Brazil.

2.2. Participants

Eligible participants in this study were 66 diagnosed with chronic nonspecific LBP and were randomized into the MA and EA. This study was approved by the ethics committee of the School of Medicine of the University of Sao Paulo (Protocol 350/13) and was registered at clinicaltrials.gov (registration number: NCT02039037). We adopted the internationally recognized standards for trial reporting (the CONSORT statement) [15] and the international standards for clinical trials of acupuncture interventions (STRICTA) [16]. The approach used for this trial was previously described in Efficacy of acupuncture and electroacupuncture in patients with nonspecific low back pain: study protocol for a randomized controlled trial [17].

The patients of study were recruited by phone through a waiting list in Specialized Rehabilitation Services - SER in Sao Paulo, Brazil and diagnosed by an orthopedist that followed the inclusion and exclusion criteria. After that, a blinded physiotherapist to treatment allocation, screened patients to confirm eligibility criteria, collected demographic and anthropometric data and assessed outcomes.

2.3. Inclusion and exclusion criteria

Patients are eligible for study inclusion if they: have chronic nonspecific LBP at least 3 months, age between 20-60 years old and a minimum pain intensity score of 3 on Numeric Rating Scale (NRS) [18]. Patients are ineligible if they: have fear of needles, previous surgery on the spinal column, known or suspected serious spinal pathology (fractures, tumors, inflammatory, rheumatologic disorders, or infectious diseases of the spine), severe cardiopulmonary disease, pregnancy, implantation of metal implants, and an inability to understand the written and spoken Portuguese language. All participants were invited to sign the participant consent form.

2.4. Randomization and blinding

Randomization was conducted using Microsoft Excel for Windows software by a previously trained evaluator who was not involved in the recruitment of the participants. The allocation was concealed using consecutively numbered and sealed opaque envelopes. After the baseline assessment, eligible participants were referred to the physical therapist overseeing the treatment, who randomized the patients to the different treatments. The assessor was blinded to the treatment allocation in the two groups. Given the nature of the interventions, it was not possible for the therapist or patients to be blinded.

The sample size calculation was designed to detect a clinically important difference for the outcomes of pain and disability. For pain intensity, a difference of two points for pain intensity as measured by the NRS (estimated standard deviation (SD) = 2 points) and a difference of four points for functional disability as measured by the Roland Morris Questionnaire (estimated SD of 4.9 points) [19,20]. The specifications were $\alpha = 0.05$, statistical power = 80%, and a possible dropout of 15% of participants. Following these parameters, 33 patients were placed in each group, total of 66 participants.

The assessments were conducted at baseline, six weeks (after treatment discharge), three months follow ups with the results. All measurements were conducted by a trained physical therapist blinded to group allocation and the primary analysis followed the intention-to-treat principle. All the questionnaires used have been validated for Brazilian-Portuguese versions of the scales [21-24].

2.4.1. Primary outcomes

To standardize outcome reporting in clinical trials of patients with nonspecific low back pain, an international multidisciplinary panel recommend physical functioning, pain intensity, and health-related quality of life (HRQoL) as core outcome domains. Hence, we have chosen pain and disability as primary outcomes [25].

2.4.1.1. Pain Intensity. Pain intensity was assessed using the NRS. The NRS is an 11-point scale ranging from 0 to 10, with 0 indicating the absence of pain and 10 indicating unbearable pain. Participants were asked to rate their average pain levels for the week prior to the assessment [26,27].

2.4.1.2. Disability. The Roland Morris Disability Questionnaire (RMDQ) [20] consists of 24 questions that focus on the regular activities of daily life, and it is used to assess functional disability. Each affirmative answer corresponds to 1 point, and the final score is determined as the total number of points. The total score ranges from 0 to 24, and higher scores reflect increased disability and scores exceeding 14 indicate severe impairment.

2.4.2. Secondary outcomes

2.4.2.1. Quality of Pain. The McGill Pain Questionnaire provides a multidimensional assessment of pain. It consists of 77 descriptors of the quantity and quality of pain that are grouped into four major domains (sensory, affective, evaluative, and miscellanea) and 20 sub-domains. For each descriptor, intensity values are assigned on a scale of 1–5. The questionnaire is used to describe pain experience, and the score corresponds to the sum of the aggregated values. The maximum scores are as follows: sensory = 41, affective = 14, evaluative = 5, miscellanea = 17, and total = 77 [26].

2.4.2.2. Depression. The Beck Depression Inventory (BDI) is an instrument that assesses the severity of depression. The original rating scale consists of 21 items that assess symptoms and attitudes on a scale of 0–3. The items in the inventory evaluate the following

Table 1
Acupoints selected for use in the study.

Acupoints	Needle insertion	Major indication and actions
GB41 Gallbladder meridian	On the dorsum of the foot, the proximal angle between the fourth and fifth metatarsal bone on the lateral depression of the extensor tendon of the little finger.	Relieves joint stiffness and muscle spasms
TE5 Triple energizer meridian	Near the dorsal wrist crease between the radius	Relaxes and strengthens tendons
ST36 Stomach meridian	3 inches below the patella between the tibia anterior and the extensor digit rum longs muscle	Tiredness, fatigue caused by weakness and irritability
HT3 Heart meridian	With the elbow flexed, between the inner end of the cubital crease and the epicondyle of the Humerus	Soothes and strengthens the mind
LI4 Large intestine meridian	The dorsal side of the hand between the first and second metacarpal bone of the middle dorsal interosseous muscle, opening the thumb and forefinger in the middle of the junction line between the first and the second metacarpal bone.	Spasm in fingers
KI7 Kidney meridian	2 inches above the point R3 on the anterior medial edge of the soleus muscle.	Leg muscle atrophy Swelling
GV4 Governor vessel	The dorsal midline in the depression below the spinous process of L2.	Strengthens the lower back and knees
SP6 Spleen meridian	3 inches above the medial malleolus in the posteromedial border of the tibia.	Pain, weakness and imbalance motor and mental asthenia.
BL23 Bladder meridian	1.5 inches toward the lower border of the spinous process of the vertebra, L2. 2 cm lateral to the midline.	Bone problems, and kidney
BL30 Bladder meridian	In the region of the sacrum, 1.5 inches lateral to the middle sacral crest, at the level of the 4th posterior sacral foramen.	Hip pain, feeling cold in the lower back.
BL58 Bladder meridian	7 inches above the heel on the lateral side of the tendon of the gastrocnemius muscle.	Weakness of the muscles of the leg, leg pain, back pain
BL60 Bladder meridian	Between Achilles tendon and the edge of the lateral malleolus of the ankle on the highest point of the malleolus level.	Headache strengthens the lumbar and thoracic region

attitudes and symptoms. The scores indicate a normal state (<15), mild depression (16–20), or severe depression (>20). Higher values indicate a higher severity of depressive symptoms [23,28].

2.4.2.3. Quality of Life. The Short Form Health Survey Questionnaire (SF-36) assesses health-related qualify of life. It consists of 36 questions grouped in eight domains. For each domain, scores range from 0 to 100, and higher scores reflect better quality of life. Only the physical, general health perception, and emotional domains were used in this study [22].

2.4.2.4. Global Perceived Effect. The Global Perceived Effect Scale is an 11-point scale ranging from −5 to 5, where −5 indicates vastly worse, 0 indicates no change, and 5 indicates completely recovered. For all measures of global perceived effect (at baseline and in all follow-up evaluations), the participants were asked the following question: "Compared to when this episode first started, how you would describe your lower back pain these days?" A higher positive score indicates greater recovery, and 9 of 12 negative scores indicate a worsening of symptoms. This outcome was measured at baseline, post-treatment, and follow up intervention [18].

2.4.2.5. Kinesiophobia. The Tampa Scale of Kinesiophobia (TSK), which was developed to measure fear of movement associated with chronic LBP, is a self-applied questionnaire consisting of 17 items. Each question has four response options (strongly disagree, disagree, agree, and strongly agree) with scores ranging from 1 to 4 points. The scores for items 4, 8, 12, and 16 are inverted, and the total score is the sum of the items, which ranges from 17 to 68 points. Increased scores reflect an increased fear of movement [21].

2.4.3. Interventions

The intervention period lasted for six weeks, with one-hour sessions implemented twice per week. Both interventions were led by experienced clinician (mean years of practice for 7 years). Participants were instructed not to participate in any other intervention during the treatment period and to report any side effects during the treatment. There was no interference in the use of medication.

Patients were instructed to remain in the lateral decubitus position, comfortable clothing, barefoot, with a pillow on head and a firm pillow between knees, angle 45° of hip and knee joint flexion.

2.5. Manual acupuncture group

The MA group received a total of 23 needles (bilateral points) in many parts of body. The description of acupoints were made according to international standard terminology [29], could be identified by acronyms with their respective locations (Table 1). Each patient has received MA with stainless steel disposable acupuncture needles (0.20 mm × 15 mm, Brand: DONG BANG, East Asia) inserted perpendicularly to the skin surface at a depth of approximately 0.5 cm for 40 min. Acupuncture points were selected through of diagnosis of LBP and published previously [17], were choose points of local analgesics, stress, muscle pain, sadness and anxiety [30,31].

2.6. Electroacupuncture group

EA group completed 30 min of acupuncture same as MA group and added more 10 minutes of EA during the treatment. Electrical

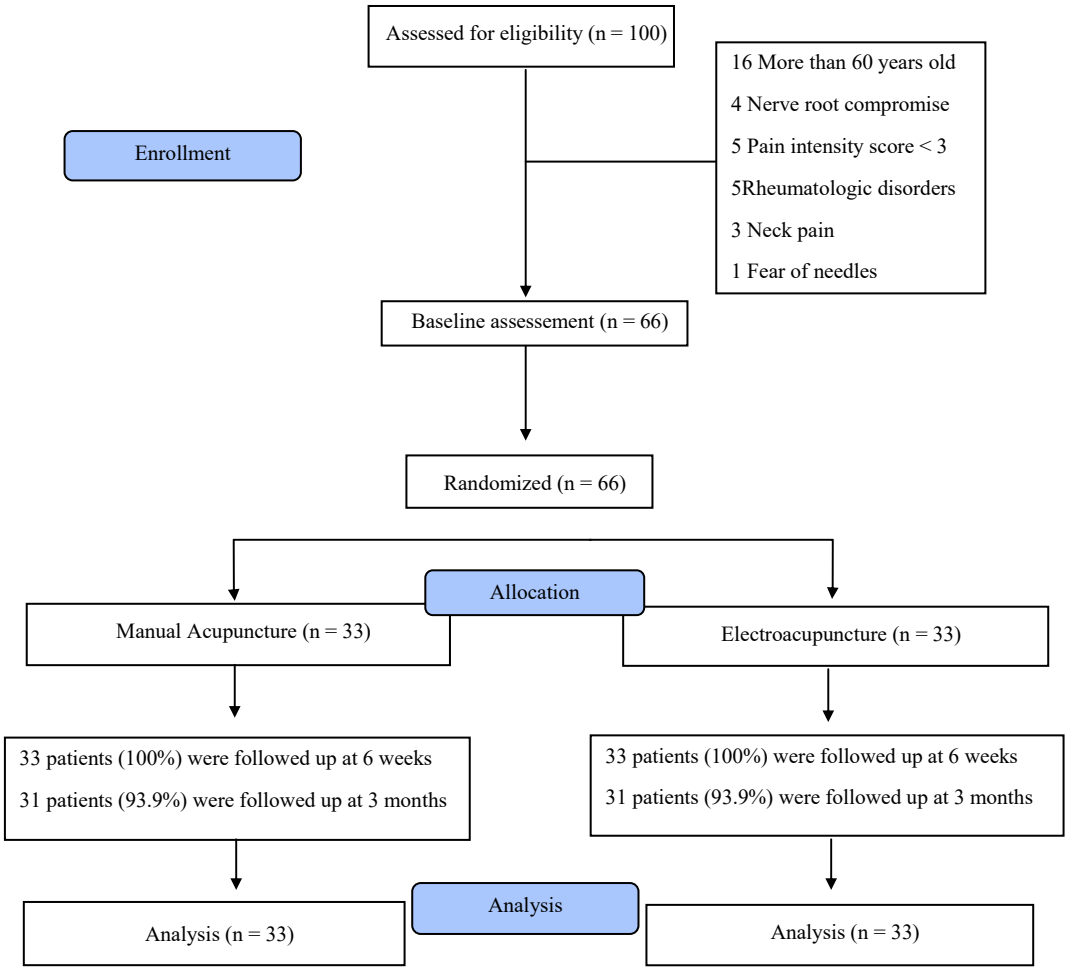

Figure 1. Flow diagram of study design.

stimulation was then applied using an EA *Accurate Pulse* 585, with a pair of electrodes connecting acupoints BL23, BL30 and another pair of electrodes connecting bilateral GV4.

Stimulation parameters were, intermittent wave, 10 Hz frequency, and 10 mA pulse width, for 10 min. The intensity of stimulation was adjusted once to reach a comfortable level during the treatment.

2.7. Statistical analysis

The statistical analysis was performed with SPSS statistical software (version 22.0; SPSS Inc, Chicago, IL, USA). USA). Kolmogorov-Smirnov test showed normal distribution of datae analyses. Descriptive data are reported as mean standard deviation or number (%). Repeated-measures analysis of variance (MANOVA) was used to investigate the effects of treatment (acupuncture vs. electroacupuncture), time (baseline, post-treatment, and 3 months' follow-up), and the interaction between the treatment groups and time. It was performed on an intention-to-treat basis.

Analysis of repeated measures was used to identify the variables that were different for each significant main or interaction effect. Pairwise comparisons were used to compare the baseline data to the data for each follow-up assessment. The confidence interval (CI) was established at 95%, and the significance level was established at $p \leq 0.05$. The flow diagram is shown in Fig. 1.

Table 2
Baseline characteristics of the subjects by group.

	MA (n = 33) Mean (SD) or n (%)	EA (n = 33) Mean (SD) or n (%)
Age (years)	49 (8.5)	46 (8.9)
Weight (kg)	72.6 (17.1)	69.8 (10.3)
Height (m)	1.62 (0.1)	1.63 (0.0)
BMI (kg/m^2)	26.9 (4.7)	26.0 (3.2)
Gender		
Male	10 (30%)	14 (42%)
Female	23 (70%)	19 (58%)
Marital status		
Single	10 (30%)	10 (30%)
Married	17 (51%)	18 (55%)
Divorced	5 (16%)	4 (12%)
Widowed	1 (3%)	1 (3%)
Occupation		
Domestic	8 (24%)	6 (18%)
General Services	11 (33%)	12 (36%)
Unemployed	6 (18%)	10 (30%)
Others	8 (24%)	5 (15%)
Duration of symptoms (months)	37 (32.2)	47 (28.6)
Use of medication	18 (54%)	18 (54%)
Physiotherapy treatment	23 (69%)	22 (66%)

The categorical variables are expressed as n (%) and the continuous variable are expressed as mean (SD); $p > 0.05$.

Table 3
Mean and difference among groups at baseline, posttreatment, and after 3 months of follow-up.

Outcomes	Unadjusted Mean (SD)		Between-group difference in score change	*p*
	MA n = 33	EA n = 33		
Pain intensity (0–10)				
Baseline	7.9(1.7)	7.8 (1.9)		
Posttreatment	3.8 (2.7)	4.2 (2.4)	−0.4 (−1.7 to 0.8)	0.51
3 months	3.7 (2.7)	4.1 (2.6)	−0.4 (−1.7 to 0.9)	0.54
Disability (0–24)				
Baseline	13.0 (5.1)	16.3 (4.8)		
Posttreatment	6.1 (5.0)	8.7 (7.4)	−2.6 (−5.6 to 0.5)	0.11
3 months	8.4 (7.3)	7.5 (7.1)	0.9 (−2.6 to 4.5)	0.59
McGill–Sensory (0–41)				
Baseline	17.3 (8.7)	20.1 (7.6)		
Posttreatment	8.0 (6.0)	9.4 (7.3)	−1.4 (−4.7 to 1.9)	0.40
3 months	9.9 (8.9)	10.5 (8.4)	−0.5 (−4.8 to 3.7)	0.79
McGill–Affective (0–14)				
Baseline	4.3 (3.3)	5.3 (3.3)		
Posttreatment	1.7 (2.6)	2.2 (3.1)	−0.5 (−1.9 to 0.9)	0.47
3 months	1.7 (2.4)	1.8 (3.2)	−0.1 (−1.5 to −1.2)	0.82
Quality of life				
General health perceptions (0–100)				
Baseline	65.3 (77.4)	60.1 (21.0)		
Posttreatment	75.4 (16.4)	65.6 (24.5)	9.8 (−0.4 to 20.1)	0.06
3 months	70.4 (26.5)	62.7 (26.0)	7.6 (−5.2 to 20.5)	0.24
Physical role functioning (0–100)				
Baseline	26.5 (36.9)	25.7 (37.2)		
Posttreatment	69.3 (41.0)	49.4 (43.7)	19.9 (−0.9 to 40.8)	0.06
3 months	52.2 (53.8)	58.3 (52.5)	−6.0 (−32.2 to 20.1)	0.64
Emotional role functioning (0-100)				
Baseline	59.5 (46.0)	53.5 (46.3)		
Posttreatment	77.5 (45.9)	74.9 (41.3)	2.6 (−18.9 to −24.1)	0.81
3 months	72.7 (48.9)	82.8 (44.9)	−10 (−33.2 to −13.0)	0.38
Mental health (0-100)				
Baseline	64.3 (23.3)	62.3 (20.1)		
Posttreatment	73.6 (18.2)	70.5 (19.7)	3.0 (−6.2 to 12.4)	0.51
3 months	69.4 (25.0)	70.1 (26.7)	−0.7 (−13.4 to 12.0)	0.91
Global perceived effect (−5 to 5)				
Baseline	−2.1 (2.6)	−2.1 (2.8)		
Posttreatment	3.4 (1.7)	2.9 (1.4)	0.5 (−0.2 to 1.3)	0.17
3 months	3.5 (1.6)	3.2 (1.1)	0.3 (−0.3 to 0.9)	0.41
Kinesiophobia (17–68)				
Baseline	41.5 (4.8)	44.9 (4.8)		
Posttreatment	38.7 (4.9)	42.8 (6.8)	−4.1 (−7.0 to −1.1)	0.00*
3 months	38.6 (7.7)	42.6 (6.7)	−4.0 (−7.5 to −0.4)	0.00*
Depression (0–63)				
Baseline	10.3 (7.7)	13.4 (8.6)		
Posttreatment	5.1 (6.6)	7.3 (9.6)	−2.2 (−6.2 to 1.9)	0.30
3 months	7.9 (9.6)	6.7 (10.6)	1.2 (−3.8 to 6.1)	0.64

#Normal range. CI = confidence interval, SF-36 = Short Form Health Survey Questionnaire. *$p < 0.05$, as determined by repeated-measures analysis of variance.

3. Results

The characteristics of the patients are described in Table 2. The groups were homogeneous in baseline. A total of 100 participants were enrolled and screened for eligibility, of whom 34 were excluded or refused to participate in the study, and 66 participants were enrolled and randomized into two groups: EA (n = 33) and MA (n = 33).

Values are presented as unadjusted means post-treatment and 3 months follow up of the pain, disability, quality of pain, quality of life, depression, global perceived effect and kinesiophobia (Table 3). We observed no differences between the groups for the variables, except for kinesiophobia, that showed a significant differences post-treatment (mean difference = −4.1 points, 95% CI = −7.0 to −1.1, p = 0.00) and difference remained also in follow up (mean difference = −4.0 points, 95% CI = −7.5 to −0.4, p = 0.00) in favor of the MA.

4. Discussion

EA and MA as a popular complementary and alternative treatment has been widely used to relieve pain in patients with LBP. Both manual and electrical acupuncture are typically lumped together to constitute scientific evidence, however, an important question of is there difference between stimulating manually or electrically? In our study, no significance difference was found for pain intensity and disability after 3 months of follow-up, the analgesic effect was maintained, which made patients getting better.

We observed that two modalities have similar effect in reducing pain intensity and disability, due to both treatments improved outcomes found these participants as quality of life, global perceived effects and depression. Our result is supported by other studies that found highly positive effects on pain and function through the collaborative treatment of MA in patients with LBP

[12,32]. The effect of acupuncture has also been investigated on biochemical parameters and was found an powerful therapeutic option to improvement of pain with an induction time of 15 to 20 minutes required for the development of an analgesic effect and proposed the participation of chemical substances in the analgesic actions of acupuncture [33]. The physiological process of acupuncture is suggested with limiting ischemia-induced apoptosis, stress-induced changes in brain-derived neurotrophic factor [3,34].

The non-difference in pain and disability also are reasonable evidence that EA has a clinically relevant pain-relieving effect on certain forms of chronic pain but is not better than MA alone. Moreover, there was no consensus, in the literature, on how to determine the optimal acupuncture treatment whose efficacy is affected by the selection of acupoints, needling depth, manipulation techniques, treatment frequency and total number of treatment sessions [9]. Other investigations in relation to previous studies on the treatment of LBP indicate that, MA and EA are rarely some stand-alone interventions and is just one aspect of a comprehensive physical therapy process [13,35,36].

One remarkable results of this study were that physiological effects thought kinesiophobia with significant results. It is known from other studies that psychosocial issues may play an important role in guiding the treatment of patients with chronic LBP, being responsible for the development and maintenance of pain [37,38] and the patients who responding to acupuncture treatment showed significant improvement in sleep pattern, activity repertoire, and analgesic consumption compared with the placebo group [39]. Even though, the main outcomes were not focused in psychological improvement of LBP, the acupoints were chosen based in local analgesic action, anxiety, and emotional points it appears to have a significant effect in the treatment.

The results of the present study are considered applicable to patients with chronic LBP of a similar intensity and disability level and to healthcare professionals who perform MA and EA. Furthermore, future studies including a longer follow-up periods are now needed to observe the effectiveness of EA and MA in patients with chronic, acute and sub-acute LBP.

Study limitations; The main limitation of this study was that the therapist and patients were not blinded to group allocation. However, it is not possible to blind therapists and patients in a randomized controlled trial with acupuncture.

Other possible limitation, because of budgetary and quality issues when dealing with sham/placebo, this study eschewed what is typically a mainstay of TCM practices.

5. Conclusion

In conclusion, the results of this trial suggest that EA and MA have similar effects in terms of reducing pain, disability, quality of life, global perceived effect, and depression in patients with chronic low back pain.

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Declaration of Competing Interest

None declared.

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