Acupuncture for Chronic Low Back Pain: A Multicenter, Randomized, Patient-Assessor Blind, Sham-Controlled Clinical Trial

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Abstract

Study Design. Multicenter, Randomized, Patient-Assessor Blind, Sham-Controlled Clinical Trial.

Objective. To investigate the efficacy of acupuncture treatment with individualized setting for reduction of bothersomeness in participants with chronic low back pain (cLBP).

Summary of Background Data. Low back pain is one of the main reasons of disability among adults of working age. Acupuncture is known as an effective treatment for chronic
low back pain, but it remains still unclear whether acupuncture is superior to placebo.

**Methods.** One hundred thirty adults aged 18-65 with non-specific LBP of lasting for at least the last 3 months was participated in the three Korean medical hospitals in Korea. Participants got individualized real acupuncture treatments or sham acupuncture treatments over 6 weeks (twice a week) from Korean medicine doctors. Primary outcome was change of Visual Analogue Scale (VAS) score for bothersomeness of cLBP. Secondary outcomes included VAS for pain intensity and questionnaires including Oswestry disability index (ODI), General health status (SF-36), and Beck’s depression inventory (BDI).

**Results.** There were no baseline differences observed between two groups except ODI. One hundred sixteen participants finished the treatments and 3-, 6-month follow ups with fourteen subjects’ drop-out. Significant difference of VAS for bothersomeness and pain intensity of cLBP have been found between two groups (p<0.05) at the primary end point (8 week). In addition, those two scores have been improved continuously until 3-month follow up (p=0.011, p=0.005, respectively). ODI, BDI and SF-36 scores were also improved in both groups without group difference.

**Conclusion.** This randomized sham-controlled trial suggests that acupuncture treatment show the better effects on the reduction of the bothersomeness and pain intensity than sham-control in participants with cLBP.

**Key words.** Acupuncture, Chronic low back pain, Clinical trial, Visual analogue scale
Level of Evidence: 2

To investigate the efficacy of acupuncture in participants with chronic low back pain (cLBP), participants got real or sham acupuncture. Difference of VAS for bothersomeness has been found between two groups after treatments. It suggests that acupuncture shows the better effects on the reduction of the bothersomeness than sham-control in cLBP.

There is evidence that individualized acupuncture treatment reduces bothersomeness of chronic low back pain better than sham acupuncture.

There is evidence that individualized acupuncture treatment reduces pain intensity of chronic low back pain better than sham acupuncture.

No significant effect was observed on disability, depression, or general health by individualized acupuncture treatment compared to sham acupuncture.

There was no significant adverse event by acupuncture treatment.

Introduction

Low back pain (LBP) is a common public health issue, and it is one of the main causes of disability among adults of working age [1]. About two-thirds of adults suffer from LBP sometime in their lives [2]. LBP is classified as chronic when it persists longer than 3 months, and chronic LBP (cLBP) is frequently associated with the non-specific LBP [3].
Identifying one definite cause of non-specific cLBP and treating this cause properly is usually difficult, because of the individual, psychological, and workplace associated contributing factors [4].

Patients with LBP are often dissatisfied with conventional forms of medical care that include medication, physical therapy, and exercise [5]. Acupuncture is one of the most often used interventions for the treatments of LBP as a complementary and alternative medical therapy [6]: specifically in China, Taiwan, and Korea, where acupuncture has a much longer tradition.

So far, some meta-analyses of randomized-controlled clinical trials (RCTs) of acupuncture have supported to its efficacy [7,8]. Acupuncture has been proven as an effective supplement to other forms of conventional medical therapy for non-specific cLBP [9]. The recent Cochrane Back Review Group supported the evidence that acupuncture can be a useful complementary treatment to other forms of conventional therapy for cLBP [7,10]. However it remains controversial whether real acupuncture is superior to placebo [11]. Studies have demonstrated both real and sham acupuncture are effective for cLBP, and other studies have suggested that real acupuncture is not more effective than sham acupuncture [12-14]. Therefore, acupuncture’s effectiveness may involve a placebo effect [8,13,14]. However, the results of one study have suggested some benefit of acupuncture over sham acupuncture [15].
These inconclusive results reflect the low methodological quality, small sample size, and other factors such as inherent difficulties in the use of controls (e.g., placebo and sham acupuncture). One of the most important problems is adopting proper controls. So far, the controls used most often have been no treatment [16], sham interventions [12,13,15-17], and other interventions that include massage, conventional therapy, transcutaneous electrical nerve stimulation and spinal manipulation [18,19]. Sham intervention has been tried with minimal acupuncture at non-acupuncture points [13,20-22] and non-penetrating sham acupuncture [15]. In this study, non-penetrating sham acupuncture at non-acupuncture points was used to apply the most appropriate placebo treatment. On study reported the use of similar sham acupuncture, but it was applied at the most painful spot and the result was assessed once only after the treatment [12].

In this trial, we investigated the efficacy of acupuncture for cLBP by adhering to revised STandards for Reporting Interventions for Clinical Trials of Acupuncture (STRICTA) recommendations and Consolidated Standards of Reporting Trials (CONSORT) guideline [23] as a way of overcoming the previous shortcoming of methodology.

Methods
**Study design**

A multicenter, two parallel, randomized, sham-controlled clinical trial was conducted in three hospitals in Korea from October 2008 to June 2010. It was approved by the each institutional review board. After screening, participants were randomized into two groups (real acupuncture and sham acupuncture) by central allocation. Randomized participants completed a questionnaire that solicited information regarding age, gender, marital status, occupation, education, and medical history. The blinding credibility of the treatments was evaluated at the end of the treatment.

**Study participants**

Patients aged 18 to 65 years who have non-specific cLBP were considered according to a battery of eligibility criteria. Inclusion criteria were cLBP lasting for at least the last 3 months, 10 cm visual analog scale (VAS) for bothersomeness of LBP exceeding 5, and non-specific, uncomplicated LBP that was intact on neurological examination. Exclusion criteria were sciatic pain (i.e., if a patient reported the typical radiating pain in leg as well as one or more neurological indications of nerve root tension or neurological deficit [24]); pain mainly below the knee; serious spinal disorders including malignancy, vertebral fracture, spinal infection, inflammatory spondylitis and cauda equine compression, history of previous spinal surgery or scheduled surgery to address a chronic disease that could interfere with treatment effects (e.g., cardiovascular disease, diabetic neuropathy, fibromyalgia, rheumatoid arthritis, dementia and epilepsy); acupuncture treatment for LBP.
during the previous month; conditions that could compromise the safety of acupuncture (e.g., clotting disorders, taking anticoagulant agent, pregnancy and seizure disorders); severe psychiatric or psychological disorder; and history of use of corticosteroids, narcotics, muscle relaxants or herbal medicine to treat LBP.

**Recruitment and randomization procedures**

Participants were recruited through advertisements in local newspapers, the hospital’s monthly magazine, the hospital’s website, and bulletin boards. Participants were asked to answer questions and were diagnosed to determine eligibility. If recruited participants were eligible and agreed with the procedures of this trial, written informed consent was obtained. The patients were randomized per center and allocated to one of the two groups using a block randomization by computer generation. The random code was generated by the medical statistician and was kept by a clinician who did not contact patients. To ensure balance within the two groups, stratified block randomization was employed. The exact procedures of this clinical trial have been published [25].

**Education of acupuncture practitioners**

Licensed Korean Medicine Doctors (KMDs, at least 3 years of experience) who specialized in Korean Rehabilitation Medicine (expert in acupuncture for LBP) typically took the educational courses to adhere to the study protocol. In those courses, KMDs practiced how to use sham acupuncture device to maintain blinding of the participants, and shared the
methods of acupuncture treatment mentioned in the protocol.

Treatments of acupuncture and sham acupuncture

Both groups received 12 acupuncture sessions (approximately two times a week for 6 weeks). At the first visit, participants were given an exercise manual for LBP patients and instructed about the manual-specified appropriate posture and exercises for LBP. The patients were requested to do the exercises everyday and try to maintain the correct posture. However, the amount of exercise that was actually done depended on their individual spontaneity. Participants were asked to complete more than 80% of the 12 possible treatments. Participants were notified that they would be dropped from the study if they received any other additional therapy, such as analgesics or physical treatments, before the primary endpoint of 8 weeks.

Interventions

Real acupuncture for treatment group

To make the real acupuncture treatment reflect an ordinary clinical practice condition, participants received individualized acupuncture treatment. That treatment was accomplished by selecting a group of acupuncture points that participating KMDs predefined. Acupuncture points were chosen according to the three types of meridian
patterns identification (Fig. 1). Other acupuncture points could be used according to the
diagnosis. Treatment was given using sterile, disposable stainless steel needles (40 mm x
0.25 mm; Dongbang Acupuncture, Kyunggi-do, Korea) with the same tube used for the
sham acupuncture device. The needles were inserted perpendicular to a depth of 5–20 mm
depending on the acupuncture point, which was followed by manual stimulation by
bidirectional rotation to induce *Deqi* sensation. *Deqi* was defined as a dull, localized, and
aching sensation, which signaled the attainment of *qi* [26]. After the *Deqi* sensation was
achieved, the needles were left in place for 15–20 minutes.

**Sham acupuncture for control group**

The treatment was carried out using the same technique and protocol as real acupuncture,
except for the use of a semi-blunt needle on non-acupuncture points without penetration.
Non-penetrating sham needles (Acuprime, Exeter, UK) [27] were used. They have been
shown to be a credible sham acupuncture by Korean patients [28]. Eight predefined points
at the lower back unrelated to traditional acupuncture points were used: 1 cm below from
Weiyang (BL39, which is acupuncture point 39 of Bladder meridian), 1 cm lateral to
Ganshu (BL18), 1 cm lateral to Pishu (BL20), and 2 cm above from Huantiao (GB30), all
bilaterally.
Outcome measures

Primary outcome measure

The primary outcome measure was VAS for bothersomeness of LBP. To understand the impact of cLBP on the patients’ life, VAS for bothersomeness was chosen instead of pain intensity. The patients were asked to mark, on a 10 cm VAS (0, absence of bothersomeness; 10, the worst bothersomeness imaginable), the average degree of bothersomeness due to LBP experienced within the most recent one week from the day of the assessment. This measurement has substantial validity [20]. Bothersomeness of LBP was measured at week 0, 6, 8, 12, and 24. The primary endpoint was the 8-week follow-up (i.e., 2 weeks after finishing all of the treatments).

Secondary outcome measures

VAS for pain intensity is a simple method evaluating the subjective intensity of pain. Pain intensity was measured in the same way as VAS for bothersomeness. Validity of its reliability has been demonstrated [29,30]. The Oswestry Disability Index (ODI) [31] was used to measure back pain-related dysfunction. The ODI consists of 11 questions about daily activities related with LBP; however, we used the Korean version of ODI [32] that excluded the sex life item. The reason for the exclusion was to avoid risk of bias, since most Koreans are reluctant to answer the question because of the Confucianism tradition.
Health-related quality of life was measured using the well-validated SF-36 [33]. A higher score is indicative of a better general health status. In our study, the validated Korean version of SF-36 [21] was used. The Korean version of the Beck’s Depression Inventory (BDI) [22] is a 21-item self-administered questionnaire. It provides a quantitative measure of depression symptoms. Validated Korean version of credibility test first proposed by Vincent & Lewith [34] was used to assess the expectation for acupuncture treatments at the beginning of the research.

Safety

To monitor safety of acupuncture, participants were asked about adverse events at each visit. If any serious adverse event occurred, detailed events were announced to the particular institutional review board and direct actions were supplied to those involved.

Statistical analyses

To determine appropriate sample size, VAS mean difference between two groups 1.5 and standard deviation 2.73cm were assumed with significance level(α)=0.05 and power(1-ß)=0.80. For the equal allocation for the two groups, total sample size considering drop-out rate of 20% was calculated as 130 subjects, which means that at least 104 subjects would finally be required after drop-outs. We performed the Shapiro-Wilk normality test to determine whether or not the sample values followed a normal distribution and finally assumed normality according to the test result. For all statistical analysis, SPSS Win.

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Significance level was set at $p$-value<0.05. Per-protocol (PP) analysis included all participants randomized and followed up until last follow-up point.

**Description of baseline characteristic and homogeneity test of two groups**

For the description of baseline characteristics, mean with standard deviation (SD) for continuous data and frequency with percentage for dichotomous data was described. Also for the homogeneity test of baseline characteristics between two groups, two sample t-test for continuous data and Chi-square test for dichotomous data was performed.

**Efficacy**

Two sample t-test was used for outcome measurements at baseline and 8 weeks for the comparison between two groups. Also, 95% confidence interval (CI) was added for all analysis. A mixed model approach of repeated measure two factor analysis was used to analyze the difference and mean change among baseline, 6, 8, 12, 24 weeks VAS, difference and mean change between groups, interaction between groups and periods.

**Results**

**Study recruitment and follow-up**
Figure 2 illustrates the flow of participants through the trial. A total of 142 participants responded to the recruitment materials and 130 (91.6%) were eligible. The main reasons for ineligibility were less than 3 months of LBP, sciatica, previous acupuncture within 1 month, and inability to attend treatment visits. Twelve patients dropped out during the treatment and one patient was eliminated after finishing all the treatments because of pregnancy. Measurements were obtained for 90% of the sample at 2 months (n=117), for 89% at 3 months (n=116), and for 89% at 6 months (n=116). Analyses included 116 participants for the primary and secondary outcome at 2, 3, and 6 months.

Baseline characteristics

Table 1 shows the baseline characteristics and outcome measurements. There was no relevant difference between the groups in so far as the potentially prognostic factors (p>0.05) and no significant difference between the groups in the scores (p>0.05) related with cLBP, except for ODI (p<0.05). To evaluate the effect of psychological factors on the improvement of symptoms, the expectation and BDI scores of participants were calculated. Credibility test score denoted the patients’ positive expectation. There was no significant difference in expectation or BDI scores (p>0.05).

Efficacy
Primary outcome measure

Mean VAS for bothersomeness scores for the real acupuncture groups decreased 3.36 points, compared with 2.27 points for participants receiving sham acupuncture at the primary endpoint. The difference was significant by two sample t-test ($p<0.05$). There was significant interaction between “periods” and “groups” by repeated measure two factor analysis ($p<0.05$) (Table 3).

Secondary outcome measures

All of the secondary outcomes of both groups were improved during the entire trial ($p<0.01$), and the improvements of the real acupuncture group were greater than the sham acupuncture. However, real acupuncture was significantly more effective only in the VAS for bothersomeness and pain intensity at the primary endpoint and all over the follow-up timepoints ($p<0.05$) (Table 2, Figure 3).

Adverse events

Sixteen participants reported 27 minor to moderate adverse events that they considered them as symptoms possibly related to treatment (Table 4). Any of them was not persisting over one week and no serious adverse events were reported.
Discussion

The purpose of this study was to clarify the efficacy of acupuncture compared with sham acupuncture in the management of cLBP with rigorous methodology. Although the main results showed that there was a positive improvement in both groups, the significant superiority of real acupuncture over sham acupuncture with no additional treatment has been clearly demonstrated for the reduction of symptoms.

Sham acupuncture method usually consists of minimal acupuncture and non-penetrating acupuncture. Minimal acupuncture penetrates skin very slightly. Non-penetrating sham acupuncture uses semi-blunt needle being in contact with skin. In this study, sham acupuncture without penetrating was used. Minimal needling acupuncture is usually thought to be uninfluential, but there is also stimulation by penetration. It is possible that superficial penetration could potentially analgesic stimulation. According to Harris et al [35], the neurotransmitter system mediates the analgesic placebo effects related with acupuncture therapy. However, in spite of the neurotransmitter system evoked by real acupuncture in the short-term and the long-term, there was no short-term and long-term effects in non-penetrating sham acupuncture group. Those findings could suggest that there may be divergent neurotransmitter pathways mediating the analgesic effects of acupuncture by penetration. Therefore, non-penetrating sham acupuncture can be the most proper method as a placebo in an acupuncture trial.
In this trial, every treatment was performed with eliciting Deqi. Elicitation of Deqi is one of the major factors in acupuncture treatment [26]. However, the trials so far did not lead to Deqi when serving acupuncture treatment.

Since patients got real individualized acupuncture treatment that is geared to the symptoms and condition of each patient by KMDs, patients in the real acupuncture group could benefit more than the sham acupuncture group. According to the revised STRICTA [23], characteristics of the practitioners including qualifications or affiliation, years in acupuncture practice could be relevant to the trial.

If the efficacy of real acupuncture could be clarified, how can we explain the mechanism of the sham acupuncture that was manifest as improvement without any other treatments? The purpose of sham vs. real acupuncture is to distinguish the physiological effect of acupuncture from the psychological placebo effects. Acupuncture is complicated to evaluate because it is difficult to isolate the characteristic or specific effects of the technique from the non-specific ones [36]. We calculated positive patients’ expectation with a credibility test questionnaire and depression with the BDI questionnaire to elucidate the psychological effects. As a result, there was no significant difference between the groups at the baseline, but both of those groups expressed optimism that acupuncture would be helpful for their cLBP in the credibility test. It is possible to assume that this expectation worked as one of factors in the beneficial mechanism of sham acupuncture. But, as seen in
Table 5, the blinding of this research was maintained, the expectation mechanism could work in both groups. Correlation between higher baseline depression score and higher pain scores at the end of treatment using sham acupuncture has been reported [37]. However, the relatively low BDI score of participants in this research make it difficult to affirm that effect of psychosomatic pain of participants be a significant variable. But, in a report from Korea [38], cLBP patients have difficulty in expressing emotions like anger, depression and sensitivity. And the longer pain persists, the less awareness of their depression they are getting. Therefore, more specific methodologies are required to use BDI score as a primary factor assessing cLBP. According to the previous study, in addition to the needling itself, several aspects of acupuncture could contribute to its effectiveness, including the individualized treatment [39], the practitioner’s skills at developing good therapeutic relationships [40], process benefits such as protected time and attention from the practitioner [41], and the widely reported relaxing experience of the treatment itself [42]. And there was still stimulation by touching skin in sham acupuncture, one functional magnetic resonance imaging experimental research reported that superficial and deep acupuncture needling are associated with imaging patterns that have no significant differences [43]. The finding supports the results that there are equivalent therapeutic outcomes of real and sham acupuncture that are claimed by acupuncture researches for cLBP using superficial acupuncture needling as a placebo. Furthermore, it is possible to have influenced on the beneficial mechanism of sham acupuncture that both groups were advised to do exercise during the research period. Among them, since relationship or attention is a kind of psychological support, depression or positive expectation or any other factors related with psychological aspects could be a parameter affecting the patient’s
Acupuncture is a relatively safety treatment for cLBP. Substantial adverse events were not severe and disappeared in a short period. Most intriguingly of all, there were similar adverse events between two groups as well.

To our knowledge, this is the first RCT for non-specific cLBP performed with non-penetrating sham acupuncture. It was performed as a RCT, but it could not be a practitioner blind trial because of distinct characteristics of acupuncture. Thus, this study was conducted as a patient-assessor blinded study. This could be another bias since practitioners (eight KMDs delivered the treatment) know real acupuncture group.

In conclusion, this study contributes evidence of acupuncture intervention compared with non-penetrating sham acupuncture for the treatment of non-specific cLBP.

Reference lists


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List of Figures

Figure 1. Three types of meridian patterns.

Figure 2. CONSORT flow of this trial.
Figure 3. Mean VAS for bothersomeness scores of cLBP (A), VAS for pain intensity scores (B), ODI scores (C), SF-36 scores (D) and BDI scores (E), and 95% confidence intervals by treatment group and time (week). There were significant improvements of scales only in the VAS for bothersomeness ($p<0.05$) and pain intensity ($p<0.01$) of cLBP in real acupuncture group, compared with the sham acupuncture group by repeated measure ANOVA (Table 2).

Table 1. Baseline characteristics and outcome measurements of the participants with cLBP.

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<th>Sham acupuncture</th>
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<td>(n=59)</td>
<td>(n=116)</td>
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<td>24.19±3.70</td>
<td>24.03±3.52</td>
<td>0.620 $^a$</td>
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<td>98(84.5)</td>
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<th>VAS for bothersomeness</th>
<th>VAS for Pain intensity</th>
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<th>SF-36</th>
<th>BDI</th>
<th>Expectation</th>
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<td>24.17±10.5</td>
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*a* result of two sample t-test

*b* credibility test

SD: standard deviation, BMI: Body mass index, VAS: Visual analogue scale, ODI: Oswestry disability index, BDI: Beck’s depression inventory

**Table 2. VAS for bothersomeness and pain intensity of cLBP.**

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<thead>
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<th>VAS for Acupuncture</th>
<th>baseline</th>
<th>End of treatments</th>
<th>Primary endpoint</th>
<th>3-month follow up</th>
<th>6-month follow up</th>
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<tr>
<td>pain intensity</td>
<td>Real</td>
<td>6.52±1.41</td>
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<td>3.00±2.41</td>
<td>2.78±2.32</td>
<td>2.79±2.44</td>
</tr>
<tr>
<td></td>
<td>Sham</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Table 3. Proportion of outcome measurements improvement (mean ±SD).

<table>
<thead>
<tr>
<th>Acupuncture</th>
<th>ΔVAS for Bothersomeness</th>
<th>ΔVAS for Pain intensity</th>
<th>ΔODI</th>
<th>ΔSF-36</th>
<th>ΔBDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of treatments</td>
<td>Real 0.54±0.34</td>
<td>0.53±0.38</td>
<td>0.42±0.25</td>
<td>0.06±0.16</td>
<td>0.42±0.48</td>
</tr>
<tr>
<td>End of treatments</td>
<td>Sham 0.32±0.28</td>
<td>0.33±0.28</td>
<td>0.25±0.43</td>
<td>-</td>
<td>0.18±0.62</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>0.000‡</td>
<td>0.001‡</td>
<td>0.01†</td>
<td>0.007‡</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Real 0.53±0.34</td>
<td>0.53±0.39</td>
<td>0.42±0.39</td>
<td>0.20±0.23</td>
<td>0.39±0.56</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Sham 0.35±0.30</td>
<td>0.35±0.29</td>
<td>0.29±0.44</td>
<td>0.16±0.13</td>
<td>0.26±0.83</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>0.003‡</td>
<td>0.007‡</td>
<td>0.096</td>
<td>0.006‡</td>
</tr>
<tr>
<td>3-month follow up</td>
<td>Real 0.56±0.36</td>
<td>0.57±0.36</td>
<td>0.43±0.33</td>
<td>0.21±0.22</td>
<td>0.48±0.48</td>
</tr>
<tr>
<td>3-month follow up</td>
<td>Sham 0.35±0.34</td>
<td>0.35±0.37</td>
<td>0.28±0.50</td>
<td>0.11±0.14</td>
<td>0.30±0.62</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>0.002‡</td>
<td>0.002‡</td>
<td>0.051</td>
<td>0.005‡</td>
</tr>
<tr>
<td>6-month follow up</td>
<td>Real 0.56±0.38</td>
<td>0.56±0.41</td>
<td>0.44±0.38</td>
<td>0.20±0.23</td>
<td>0.44±0.58</td>
</tr>
<tr>
<td>6-month follow up</td>
<td>Sham 0.41±0.39</td>
<td>0.44±0.41</td>
<td>0.24±1.10</td>
<td>0.14±0.15</td>
<td>0.36±0.66</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>0.044†</td>
<td>0.118</td>
<td>0.202</td>
<td>0.093</td>
</tr>
</tbody>
</table>

Every proportion was calculated by formula below.

ΔVAS for Bothersomeness (at the end of treatments) = absolute value of [VAS for Bothersomeness (baseline) – VAS for bothersomeness (end of treatments)] / VAS for Bothersomeness (baseline)

Significances by two sample t-test

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Table 4. Adverse events (number of the reported cases, multiple answers.)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Real acupuncture (n)</th>
<th>Sham acupuncture (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>temporary worsened LBP</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>pain of acupunctured site</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>bruise of acupunctured site</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>pain, numbness or other bothersomeness of leg (including knee)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>systemic bothersomeness</td>
<td>.</td>
<td>1</td>
</tr>
<tr>
<td>(feeling sluggish or having body ache)</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>shoulder pain</td>
<td>2</td>
<td>.</td>
</tr>
<tr>
<td>pain or bothersomeness of foot</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 5. Blinding index (end of the treatments)

<table>
<thead>
<tr>
<th>Type of acupuncture received</th>
<th>Type of acupuncture participants stated they had received n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Real acupuncture</td>
</tr>
<tr>
<td>Real acupuncture group</td>
<td>14(24.56)</td>
</tr>
<tr>
<td>Sham acupuncture group</td>
<td>19(32.20)</td>
</tr>
<tr>
<td>Sum</td>
<td>33</td>
</tr>
</tbody>
</table>

Real acupuncture group; 0.07 (95% CI: -0.10, 0.24), blinded
Sham acupuncture group; -0.23 (95% CI: -0.39, -0.08), blinded