# SOUTH BAYLO UNIVERSITY

Acupuncture for Low Back Pain: A Systematic Review and Meta-analysis

by

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# Acupuncture for Low Back Pain: A Systematic Review and Meta-analysis Joanne Kim SOUTH BAYLO UNIVERSITY Research Advisor: Jaejong Kim, MD, OMD, L.Ac.

#### Abstract

Low back pain (LBP) is one of the most prevalent musculoskeletal disorders and has a considerable impact on quality of life. Increasingly, acupuncture has been used to treat LBP, but clinical evidence for its therapeutic effects and safety has not been evaluated comprehensively. This study evaluates the effect of acupuncture on LBP and provides evidence that acupuncture is a safe, effective intervention for LBP. Studies relating to acupuncture for LBP were retrieved from electronic databases, and randomized controlled trials from the studies were reviewed and analyzed. The data were synthesized, and a meta-analysis was performed using RevMan5.4 software in accordance with the PRISMA checklist. A total of 15 trials involving 2393 participants with LBP were included in the meta-analysis. The VAS score of 10 trials, involving 822 participants, was improved in the acupuncture group, compared to that of the control group [MD 0.16 (0.11, 0.21), 95% CI, P < 0.0001]  $l^2 = 55\%$ . The NPRS of twere trials involving 192 participants was lower in the acupuncture group compared to the control group; however, NPRS did not show significance [MD -0.31 (-0.92, 0.30), 90% CI, P = 0.32]  $l^2 = 0\%$ . In two trials involving 605 participants, the RMDQ was improved significantly in the acupuncture group compared to the control group [MD 0.60 (0.01, 1.18), 95% CI, P = 0.09]  $l^2 = 94$  %. In one trial involving 974 participants, the CPGS was lower in the acupuncture group compared to the control

group [MD 0.02 (-0.03, 0.07), 95%CI, P=0.48]. Regarding safety, the adverse effects were lower in the acupuncture group compared to the control group. These results suggest that acupuncture is a safe and effective method of treating LBP compared to other therapies. However, more trials with larger samples will be required to provide robust evidence as to the effectiveness of treating LBP with acupuncture.

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#### I. INTRODUCTION

Global Burden of Disease studies have defined low back pain (LBP) as pain in the posterior aspect of the body, from the lower margin of the 12<sup>th</sup> rib to the lower gluteal folds, with or without pain radiating to one or both lower limbs; this pain lasts for at least one day.<sup>1</sup>

Back pain is the leading cause of disability worldwide, preventing many people from engaging in work and everyday activities, It is also the third most common reason for physician visits.<sup>3</sup> LBP was estimated to impact 577 million people worldwide in 2017.<sup>4</sup> Each year, one-half of all working Americans report having back pain symptoms,<sup>5</sup> and LBP costs Americans at least \$50 billion in healthcare<sup>6</sup> and lost wages. There is also evidence of decreased productivity, increasing the cost of LBP to more than \$100 billion annually.<sup>7</sup>

LBP results from a variety of injuries, conditions, and diseases, including sprains, fractures, disk problems, structural problems, spondylolisthesis, arthritis, and spinal tumors.<sup>8</sup> Symptoms of LBP vary, depending on the underlying cause, and pain can range from mild-to-severe. In some cases, back-associated pain can make it difficult or even impossible to walk, sleep, work, or take part in everyday activities.<sup>8, 9</sup>

Diagnosis of LBP is typically based on patient history, symptoms, physical examination, and diagnostic results. Some patients may respond to conservative treatment. However, if conservative treatment is ineffective, the physician may order imaging studies including spinal X-ray, MRI, CT scan, and/or EMG.<sup>10, 8</sup>

Treatment options for LBP can be tailored to the individual case based on diagnosis. Treatments include medications, physical therapy (PT), spinal injections, acupuncture, spinal manipulation, spinal mobilization, and surgery. Surgery may be considered for severe LBP that does not improve after 6-to-12 weeks of non-surgical interventions.<sup>14,11</sup> As the prevalence of LBP increases, demand for safe, effective treatments has also grown.

In recent times, acupuncture has become widely accepted as a safe, effective, and economical therapy for LBP. In Traditional Chinese Medicine (TCM), the meridians and collaterals are pathways through which the body's qi and blood circulate. LBP is associated with obstructed meridians and collaterals affecting the lower back. Improper flow of qi and/or blood stagnation in the meridians, specifically in the lower back area, may contribute to LBP.

In TCM, the Kidneys govern the back, and deficiency in Kidney Yin or Yang may negatively impact the Kidney meridian in the posterior of the body, resulting in lower back weakness or stiffness.

Acupuncture is a significant element of Oriental medicine (OM), a healing tradition with a history of more than 2,500 years. Acupuncture, along with Oriental herbs, has been used to treat various diseases by unblocking the 12 meridians (channels).<sup>13</sup> The use of acupuncture and Oriental medicine treatments is on the rise. A 2007 NIH survey estimated that, between 2002 and 2007, acupuncture use among adults increased by approximately one million people,<sup>17</sup> with more than 10 million acupuncture treatments administered annually in the United States.<sup>18</sup>

The efficacy of acupuncture has been demonstrated through its use on numerous patients who have benefited from it. However, the evidence is still insufficient, limiting its widespread adoption. In the past decade, clinical trials have been conducted on the use of acupuncture for LBP, and the results have been published. The conclusions are still inconsistent and sometimes contradictory, thereby limiting the use of this treatment modality.

#### **OBJECTIVES**

The purpose of this work is to appraise critical evidence from relevant studies and present a comprehensive evaluation of the therapeutic value of acupuncture, including the efficacy of acupuncture in treating LBP.

The detailed objectives for this study are as follows:

- To analyze and evaluate the effectiveness of acupuncture in reducing pain using tools such as VAS and NPRS.
- To analyze and evaluate the effectiveness of acupuncture in reducing disability and improving quality of life using measures such as CPGS and RMDQ.
- To analyze and evaluate the effect of acupuncture on safety and adverse effects.

#### LITERATURE REVIEW

## Lower Back Pain From a Western Medicine Perspective

Low back pain (LBP) is defined as pain in the area on the posterior aspect of the body from the lower margin of the 12th ribs to the lower gluteal folds, with or without pain radiating to one or both lower limbs, lasting for at least one day.<sup>1</sup>

# **Causes:**

1. Strains and sprains – People can injure muscles, tendons, or ligaments by lifting heavy objects. Some people also strain their backs by sneezing, coughing, twisting, or bending over.<sup>8</sup>

2. Fractures – The bones in the spine can break during an accident, such as a car collision or a fall.

Disk problems – Disks cushion the vertebrae (small spinal bones). The disks can bulge from their normal position and impinge on nerves. They can also tear (herniated disks).
 With age, disks can become flattered, thereby offering less protection (degenerative disk disease).<sup>8</sup>

4. Structural problems – Spinal stenosis occurs when the spinal column is too narrow for the spinal cord. Pinching of the spinal cord can cause severe sciatic nerve pain and lower back pain. Scoliosis (curvature of the spine) can lead to pain, stiffness, and difficulty moving.<sup>8</sup>

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5. Arthritis – Osteoarthritis is the most common type of arthritis to cause lower back pain.

6. Spondylolisthesis – This condition causes the vertebrae in the spine to slip out of place, leading to low back pain and, often, leg pain.<sup>8</sup>

7. Ankylosing spondylitis – This condition causes lower back pain, inflammation, and stiffness in the spine.

8. Disease – Spinal tumors, infections, and various cancers can cause back pain. Other conditions such as Kidney stones and abdominal aortic aneurysms can cause back pain.

# **Symptoms**

Common symptoms of LBP include a dull, aching sensation in the lower back; stabbing or shooting pain that may radiate down the leg to the foot; inability to stand up straight without pain; decreased range of motion; and reduced ability to flex the back.<sup>15</sup> Some symptoms indicate a serious problem, including loss of bowel or bladder control; numbness, tingling, or weakness in one or both legs; back pain after trauma (injury), such as a fall or a blow to the back; intense, constant pain that gets worse at night; unexplained weight loss; and pain associated with a throbbing sensation in the abdomen.<sup>15</sup>

# **Diagnosis:**

1. **Physical exam** – A physical exam can help identify potential causes of pain. A typical physical exam for low back pain includes palpation, a neurologic exam, a range of motion test, a reflex test, and a leg-raise test.<sup>11</sup>

2. Spine X-ray – Producing images of bones.

3. **Magnetic resonance imaging (MRI)** – use of a magnet and radio waves to create images of bones, muscles, tendons, and other soft tissues.

4. Computed tomography (CT or CAT scan) – X-rays combined with a computer are used to create 3-D images of bones and soft tissues.

5. Electromyography (EMG) – Tests nerves and muscles and checks for neuropathy (nerve damage), which can cause tingling or numbness in the legs.

## **Treatment:**

1. **Medications** – Nonsteroidal anti-inflammatory drugs (NSAIDs) or prescription drugs for pain relief. Other medications can be used to relax muscles and prevent back spasms.

2. **Physical therapy (PT)** – Strengthens core muscle groups that support the low back, improves mobility and flexibility, and promotes proper positioning and posture.<sup>14</sup>

3. **Transcutaneous electrical nerve stimulation (TENS)** – A wearable, battery-powered device that generates electrical impulses designed to block or modify pain perception.

4. **Spinal injections** – Trigger point injections can relax knotted muscles (trigger points) that may contribute to back pain epidural steroid injections – An injection into the lumbar area of the back is given to treat low back pain and sciatica associated with inflammation.<sup>14</sup>

5. Acupuncture – Acupuncture is significant part of Traditional Chinese Medicine (TCM), widely used as a healing system in clinical practice. Acupuncture involves the insertion of thin needles into acupuncture points along the body's twelve meridians to treat various conditions.

6. **Spinal manipulation and spinal mobilization** – Chiropractic care to mobilize, adjust, massage, or stimulate the spine and the surrounding tissues.<sup>14</sup>

7. **Surgery** – If other therapies fail, surgery may be considered to relieve pain caused by worsening nerve damage, severe musculoskeletal injury, or nerve compression. Specific surgeries are selected for specific conditions/indications. However, surgery is not always successful. It can take months after surgery before a person is fully healed, and permanent loss of flexibility may result.<sup>14</sup>

## Lower Back Pain From TCM Perspective

## Causes

**Stagnation of qi and blood:** The meridians and collaterals are pathways in which qi and blood circulate. They form a web that crosses the body vertically and horizontally, joining internal organs with the skin, muscles, sinews, bones, and all other tissues, integrating each part with the whole.<sup>16</sup> Qi should travel freely through all twelve meridians in the correct direction. A lack of free flow of qi in the meridians, specifically through the low back region, can cause LBP. Blood stagnation, which can cause LBP, has various causes: One cause is back trauma, which can be caused by back injury. Back trauma can give rise to what is called "blood stagnation." The other reason for blood stagnation is a long history of qi stagnation. Qi moves the blood, and if qi stays stagnant long enough, the body fluids that are supposed to flow also begin to stagnate.

**Invasion of cold dampness:** The Kidneys are susceptible to cold wind and dampness. LBP occurs when the lower back is exposed frequently to cold, damp weather, resulting in depletion of Kidney

Yang energies. Cold dampness obstructs qi movement and causes stagnation of qi in the lower back area.

**Deficiency of Kidney:** In TCM, the Kidneys govern the back. A deficiency in Kidney Yin or Yang may negatively affect the Kidney meridian in the posterior of the body, resulting in weakness or stiffness in the lower back.

- *Etiology of Kidney-Yang (KD-Yang) deficiency:* A constitutional deficiency of Yang or weakness of the Kidney (KD) in old age, a prolonged illness, or excessive sexual activity, both of which may injure KD and produce deficiency of KD-Yang; excessive consumption of cold and raw foods may weaken Spleen-Yang (SP-Yang) and KD-Yang. Retention of dampness (resulting from SP-deficiency) over a long period may eventually lead to a deficiency of KD-Yang.<sup>16</sup>
- *Pathology of KD-Yang Deficiency:* KD-Yang deprives the bones, ears, brain, and marrow of nourishment. LBP due to deficiency of KD-Yang is often described as soreness in the lumbar region.
- *Etiology of KD-Yin Deficiency:* KD-Yin may be injured by a long chronic illness, usually transmitted from the Liver, Heart, or Lung, or depletion of body fluids after febrile disease, overwork over a period of several years, or excessive sexual activity, which depletes KD-essence, loss of blood over a long period, which causes Liver-blood deficiency leading to KD-Yin deficiency, and over-dosage of herbal medicines to strengthen KD-Yang.<sup>16</sup>
- *Pathology of KD-Yin deficiency on LBP:* Failure of KD-essence in nourishing bones gives rise to lower back pain and aches in the bones.

## **Symptoms**

1. Qi and blood stagnation – back pain is sharp and fixed.

2. Invasion of cold-dampness – feeling cold; sensation of heaviness, alleviated by warmth, gradually worsening; difficulty in rotating.

3. Kidney deficiency – soreness or weakness.

# Diagnosis

Diagnosis in Oriental medicine is based on the correspondence between a part of the body and a specific internal organ, or the entire body. The "four diagnostic methods" are used in TCM primarily to examine pathological conditions in clinical practice. The four methods are inspection (observation), interrogation (inquiring or questioning), auscultation and olfaction (listening and smelling), and palpation (pulse examination). X-rays are also sometimes recommended for patients who have been injured in falls, severely impacted by back injuries, or suffering from severe osteoporosis.

In TCM, the four diagnostic methods are carried out by examining the flexion/extension/rotational movements of the lower back, gait posture, deformation of the spine and pelvis, and radiating pain around it; taking the patient's history; asking about the condition; and palpating the spine, ligaments, and surrounding muscle with pulse examination.

Diagnosing the cause of back pain is performed by examining the external condition, followed by exploring the internal cause. Identifying the internal cause of chronic back pain is the most important factor for accurately diagnosing the condition.

## Treatment

If LBP results from stagnation of qi and blood, treatment needs to trigger the three principles: qi movement, blood nourishment, and blood circulation. If the cause is invasion of cold dampness, promoting the circulation of qi and blood is the treatment principle for pain relief. If Kidney-Yang deficiency is the cause, dispelling wind and cold and removing obstruction in meridians are the principles. If LBP results from Kidney-Yin deficiency, tonifying KD-Yang and strengthening the KD-essence are the treatment principles for relieve LBP.<sup>16</sup>

1. Acupuncture – Needles are used to penetrate the meridians. Acupuncture establishes the proper flow of qi, which increases blood circulation and supports the body's healing processes. Hence, acupuncture can be an effective treatment for LBP. If the meridians have been blocked for an extended period, or if there is a pronounced deficiency of qi and blood, acupuncture can be highly effective.

2. Herbal medicine – Individual herbs are combined to create a formula. In treating LBP, herbal medicines can help open the channels or strengthen the Kidneys.<sup>9</sup>

3. Moxibustion – Concentrated herbs are burned above the skin. Moxibustion is mainly used to warm meridians and expel cold, induce the smooth flow of qi and blood, rescue Yang from collapse, prevent disease, and promote health.

## **II. MATERIALS AND METHODS**

## Literature Search and Selection Strategy

The literature was explored using the research topics of "low back pain," "acupuncture," and "research design of randomized controlled trials" (Table 1).

 Table 1. Formation of the EBM Question Based on the PICO Rule

PICO	EBM question	
Problem	Low back pain	
Intervention	Acupuncture	
Comparison	Control	
Outcome	Primary outcome variables: visual analog scale of pain (VAS) Secondary outcome variable: various survey	
Study design	Randomized controlled trial	

Electronic databases such as PubMed and EBSCO and other relevant sources were searched for randomized controlled trials (RCTs) that involved acupuncture for low back pain (LBP) published from 2006 to 2022. The selection strategy was processed: First, "low back pain" was used as the individual search term. Second, "low back pain" and "acupuncture" were combined by the Boolean operator "AND." Third, irrelevant articles and duplicates were excluded. Fourth, "randomized controlled trial" was added by "AND." Fifth, titles and abstracts were screened for full texts. Sixth, full-text analysis was performed for the eligible studies (Figure 1).

# Inclusion/Exclusion Criteria

Participants: Patients who were diagnosed with low back pain.

**Intervention:** The experimental intervention was acupuncture therapy. Control interventions were therapies other than acupuncture. Experimental intervention (acupuncture) integrated with other treatments such as moxibustion, cupping, acupressure, and Chinese herbs, was excluded.

Outcomes: Studies included in the review reported VAS as their primary outcome.

**Study type:** In the review, only randomized controlled trials (RCT) were included. Non-RCTs such as case studies, case series, surveys, or cohort studies were excluded.

## **Data Extraction and Items**

To extract data for systematic review and meta-analyses of the selected studies, data items such as literature information, reasons for inclusion/exclusion, study design, research subject, interventions, outcomes, results, and others were extracted following the PICO method (Table 2).

## Meta-analysis of Multi-arm Trial

For multi-arm parallel-group randomized controlled trials (RCTs), 3-arm or 4-arm parallel RCTs, a two-arm comparison or a split of multi-arm trials was performed for meta-analysis.

#### Assessment of the Risk of Bias

To evaluate the risk of bias (RoB) of the selected studies, RoB software provided by RevMan 5.4 and the Cochrane Risk of Bias Assessment Tool were used. The Cochrane Risk of Bias Assessment Tool comprises seven qualitative elements: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data reporting (attrition bias), selective outcome reporting (reporting bias), and other bias (Table 3).

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Data Component	Data Item	
Literature information	• Literature ID	
	• Elterature ID	
Eligibility	• Selection or exclusion	
	• Reason for exclusion	
Methods	• Study design	
	• Period of trial	
	• If RCT	
	• Order of randomization, concealment of randomization order, blinding, and other factors to evaluate the bias	
Participants	• Sample size, clinical setting, diagnostic criteria, age, gender, comorbidity, socio-demographic characteristics, ethnicity, study timing	
Interventions	• Number of intervention groups	
	• Method of intervention, repeatability of intervention, integrity of intervention	
Outcomes	• Outcome and timing of intervention, timing of data collection, timing of report	
	• Definition of outcome (including diagnostic criteria), unit of data, value and meaning of maximum and minimum scale data	
Results	• Sample size, missing data, schema, mean and standard deviation from continuous variables, confidence intervals, p-value, significance	
Others	• Sponsor of research fund	

# **Table 2.** Formation of Data Extraction and Items

Type of Bias	Description	Relevant domains in the collaboration's "risk of bias" tool
Selection bias	Systematic differences between baseline characteristics of the groups that are compared.	<ul><li>Sequence generation.</li><li>Allocation concealment.</li></ul>
Performance bias	Systematic differences between groups in the care provided or in exposure to factors other than the interventions of interest.	<ul> <li>Blinding of participants and personnel.</li> <li>Other potential threats to validity.</li> </ul>
Detection bias	Systematic differences between groups in how outcomes are determined.	<ul> <li>Blinding outcome assessment.</li> <li>Other potential threats to validity.</li> </ul>
Attrition bias	Systematic differences between groups in withdrawal from a study.	• Incomplete outcome data.
Reporting bias	Systematic differences between reported and unreported findings.	• Selective outcome reporting.

# **Heterogeneity Analysis**

When forest plots showed that confidence intervals and the directionality of the treatment effect values did not overlap, or overlapped only to a minor extent, statistical tests for heterogeneity were performed. The statistical tests for the heterogeneity were Q statistics and Higgin's  $I^2$  statistics, with the values calculated using RevMan 5.4.

## **Q** Statistics (chi-square test)

Q statistics is the test for heterogeneity in meta-analysis. The formula for calculating the Q value is shown in Appendix I. Through the Q statistics, the distance between the treatment effect of each study and the pooled effect across studies in value was assessed.

This test also assumes the null hypothesis that "cannot find any evidence for heterogeneity" and gives a p-value to test this hypothesis. In this meta-analysis, if the p-value was greater than 0.10, the null hypothesis was adopted, and a meta-analysis of the fixed-effects model was performed. If the p-value was less than 0.10, the null hypothesis was rejected, and a meta-analysis of the random-effects model was performed.

# Higgin's *I*<sup>2</sup> Statistics

Higgin's  $I^2$  statistics were used to quantify heterogeneity. The degree of heterogeneity was interpreted according to the  $I^2$  value. The formula for calculating the  $I^2$  value is shown in Appendix I, and the criteria for heterogeneity analysis are as follows:

 $0\% \le I^2 \le 40\%$ : heterogeneity may not be significant.  $30\% \le I^2 \le 60\%$ : there may be moderate heterogeneity.  $50\% \le I^2 \le 90\%$ : may be substantially heterogeneous.  $75\% \le I^2 \le 100\%$ : significant heterogeneity.

#### **Meta-analysis**

The outcome measures for the meta-analysis were VAS, NPRS, RMDQ, and CPGS, and RevMan 5.4 was used to perform the meta-analysis. All the data in the review was continuous.

For meta-analysis of continuous data, sample size, mean, and standard deviation were extracted from the experimental and control groups in individual studies. The weighted mean difference (WMD) or standardized mean difference (SMD) was calculated using the extracted values. The formula for calculating the weighted average value and the standardized mean difference is shown in Appendix I.

# **Assessment of Reporting Bias**

The funnel plot was used to assess the potential reporting bias, such as publication bias, time lag bias, multiple publication bias, location bias, citation bias, language bias, and outcome reporting bias.

# **Determination of Safety and Adverse Effects**

The safety and adverse effects of the intervention were identified using the evidence from the studies.

# **III. RESULTS**

# **Study Selection**

With "low back pain" as a search term, a total of 25,621 citations were obtained from PubMed, EBSCO, and other relevant sources. After including "acupuncture," 557 articles remained to be screened. After excluding duplicates, unrelated articles, and non-randomized controlled trials, 39 articles were obtained to review their titles and abstracts. After reviewing the titles and abstracts, 10 articles were selected to read the full texts, and 10 eligible studies were selected for qualitative and quantitative evaluation (Figure 1).

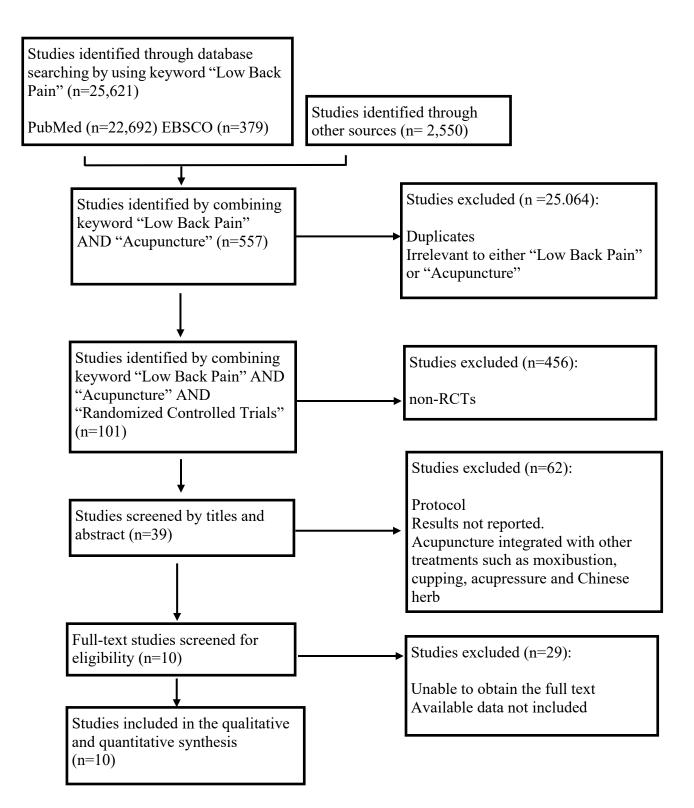


Figure 1. PRISMA Flowchart of Study Selection

#### **Study Characteristics**

The 10 selected studies consisted of 15 randomized controlled trials (RCTs), which had published in English or Chinese between 2006 and 2022. The included RCTs involved 2393 participants with LBP, and the ages of participants ranged from 18 to 74 years old. The treatment for experimental groups was acupuncture, which was compared with other therapies for LBP. The duration of the interventions was between three weeks and two months. Of these studies, 10 RCTs reported VAS scores, two reported RMDQ, two reported NPRS and one reported CPGS in outcomes.

#### **Data Extraction and Conversion**

## 1) Data extraction and item

To extract data for systematic review and meta-analysis from the selected studies, data items such as literature information, eligibility, study method, participants, interventions, outcomes, results, and others were extracted following the P-I-C-O method (Table 4).

#### 2) Conversion of the outcome data

The results of the data were extracted from the selected studies, and mean value, median value, standard deviation, and standard error among the results were confirmed to derive the mean difference and the 95% confidence interval (CI). Review Manager 5.4 (RevMan 5.4) was applied to perform the meta-analysis using the standard mean difference (SMD) and 95% CI in the experimental and control groups.

#### Meta-analysis of Multi-arm Trial

The four studies (Luo 2019, Galzov 2013, Zaringhalam 2010, Cherkin 2009) among 10 selected studies included multi-arm parallel randomized trials. To avoid error in reporting such

trials and to obtain accurate results from meta-analysis, a two-arm comparison, or a split of multi-arm trials were performed.

Luo (2019) is a 3-arm parallel randomized controlled trial and was split into two comparisons of a two-arm randomized controlled trial such as Standard acupuncture vs Usual care group, and Hand-ear acupuncture vs Usual care group.

Glazov (2013) is a 3-arm parallel randomized controlled trial and was split into two comparisons of a two-arm randomized controlled trial such as Low dose laser acupuncture vs Sham acupuncture, and High dose laser acupuncture vs Sham acupuncture.

Zaringhalam (2010) is a four-arm parallel randomized controlled trial and was split into three comparisons of a two-arm randomized controlled trial such as Acupuncture vs Control group (Control group received no pain reduction treatment), Acupuncture + Baclofen (30 mg a day) vs Control, and Acupuncture + Baclofen vs Baclofen only.

Cherkin (2009) is a 3-arm parallel randomized controlled trial and was split into two comparisons of a two-arm randomized controlled trial such as Standardized acupuncture vs Usual care group, and Individualized acupuncture vs Usual care group.

Data Component	Data Item	
Literature information	• Chen et al. $2022^{20}$	
Eligibility	• Selection or exclusion: five inclusion criteria and eight exclusion criteria	
Methods	<ul> <li>A two-arm parallel randomized controlled trial</li> <li>Frequency and period of trial: six times per week, for total of three weeks of treatment</li> <li>Period of follow-up: six months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: unclear</li> </ul>	
Participants	<ul> <li>Sample size: 138 <ul> <li>Experimental group (n=64, five drop-off and</li> <li>others)</li> <li>Usual care groups (n=62, seven drop-off and</li> <li>others)</li> </ul> </li> <li>Clinical setting, diagnostic criteria, age, gender,</li> <li>comorbidity, socio-demographic characteristics,</li> <li>ethnicity, study timing</li> </ul>	
Interventions	<ul> <li>Number of intervention groups: one</li> <li>Method of intervention: warm acupuncture on</li> <li>Shenshu, Yaoyangguan, Mingmen, Weizhong, and Ashi points</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>	
Outcomes	<ul> <li>VAS</li> <li>Short form of McGill pain questionnaire (SF-MPQ)</li> <li>Oswestry disability index (ODI) score, finger-to-floor distance (FFD), Schober test distance, fear-avoidance beliefs questionnaire (FABQ) score, and Yang deficiency and cold-dampness blockage score</li> <li>Other outcomes: serum levels of tumor necrosis factor-α (TNF-α), interleukin (IL)-1β, IL-6, and thromboxane B2 (TXB2)</li> <li>At baseline, four weeks</li> </ul>	
Results	<ul> <li>VAS</li> <li>Baseline: 5.31±0.86 vs. 5.26±0.83</li> </ul>	

# **Table 4**. Data Items Extracted From the Selected Literature

	• Three weeks: 1.13±0.25 vs. 1.72±0.39
	• ODI
	• Baseline: 34.69±4.87 vs. 34.82±4.93
	• Three weeks: 6.68±1.04 vs. 11.83±1.67
	• SF-MPQ(PRI)
	• Baseline: 16.75±2.77 vs. 16.67±2.79
	• Three weeks: 4.01±0.73 vs. 6.94±1.12
	• SF-MPQ(PPI)
	• Baseline: 2.96±0.44 vs. 2.92±0.43
	• Three weeks: 0.65±0.15 vs. 0.94±0.16
Others	• Sponsor of research fund; the youth project of the
	National Natural Science Foundation of China: 81102627

Data Component	Data Item	
Literature Information	• Li et al. 2020 <sup>21</sup>	
Eligibility	• Selection or Exclusion: five inclusion criteria and	
	six exclusion criteria	
Methods	• A two-arm parallel randomized controlled trial	
	• Frequency and Period of trial: three times a week,	
	<ul><li>total of four weeks of treatment.</li><li>Period of follow-up: six months</li></ul>	
	<ul> <li>Order of randomization: high</li> </ul>	
	<ul> <li>Concealment of randomization order: unclear</li> </ul>	
	• Blinding: unclear	
Participants	• Sample size: 70	
	• Experimental group (n=35)	
	• usual care groups (n=35)	
Interventions	• Number of intervention groups: one	
	• Method of intervention:	
	Yaoyangguan, bilateral Shenshu, Weizhong, Zhibian, and lesion sites, Jiaji and Ashi points were treated with	
	filiform fire needling	
	<ul> <li>Repeatability of intervention: high</li> </ul>	
	• Integrity of intervention: high	
Outcomes	• VAS	
	Oswestry disability index (ODI)	
	• Other outcomes: Surface electromyography detection,	
	The average electromyography value (average electromyographic, AEMG), root mean square (root mean	
	square (RMS), median frequency (MF) and average bit	
	frequency (average frequency, AMF). Dynamic muscular	
	endurance assessment.	
	• At baseline, four weeks	
Results	• VAS	
	• Baseline: 5.50 (4.80, 6.20) vs. 5.45 (4.80,	
	6.10) Eour weeks: 2.10 (1.90, 2.30) vs. 2.80 (2.40	
	<ul> <li>Four weeks: 2.10 (1.90, 2.30) vs. 2.80 (2.40, 3.20)</li> </ul>	

# **Table 4.** Data Items Extracted From the Selected Literature (cont.)

	<ul> <li>ODI</li> <li>Baseline: 43.0 (37.0, 49.0) vs. 44.0 (38.0, 50.0)</li> <li>Four weeks: 23.0 (21.0, 25,0) vs. 31.0 (28.0, 34.0)</li> </ul>
Others	• Sponsor of research fund; N/A

Data Component	Data Item	
Literature Information	• Luo et al. 2019a <sup>22</sup>	
Eligibility	• Selection or exclusion: two inclusion criteria and six exclusion criteria	
Methods	<ul> <li>Two-group comparison from a three-arm parallel randomized controlled trial</li> <li>Period of trial: seven weeks</li> <li>Period of follow-up: six months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: unclear</li> </ul>	
Participants	<ul> <li>Sample size: 98</li> <li>Standard acupuncture (n=50)</li> <li>Usual care groups (n=48)</li> </ul>	
Interventions	<ul> <li>Number of intervention groups: one (out of two)</li> <li>Method of intervention: <ul> <li>Six acupoints that are commonly used for the treatment of LBP (BL 23 bilateral, BL 40 bilateral, and KD 3 bilateral) on the low back and lower leg</li> <li>All acupoints were needled for 15 min, with needle stimulation by twirling the needles for 10 min and again at 10 min prior to removal.</li> </ul> </li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>	
Outcomes	<ul> <li>VAS</li> <li>Roland Morris Disability Questionnaire (RMDQ)</li> <li>At baseline, two months and six months</li> </ul>	
Results	<ul> <li>VAS</li> <li>Baseline: 6.92 (6.33, 7.51) vs. 6.73 (6.17, 7.29)</li> <li>Two months: 5.40 (4.77, 6.03) vs. 5.92 (5.42, 6.41)</li> <li>Six months: 4.16 (3.64, 4.68) vs. 5.31 (4.85, 5,78)</li> <li>RMDQ</li> <li>Baseline: 12.98 (10.66, 15.30) vs. 13.50 (11.49, 15,51)</li> <li>Two months: 7.08 (5.12, 9.04) vs. 12.31 (10.30, 14.32)</li> </ul>	

**Table 4.** Data Items Extracted From the Selected Literature (cont.)

	<ul> <li>Six months: 6.86 (5.09, 8.63) vs. 11.75 (9.92, 13.58)</li> </ul>
Others	Sponsor of research fund; Traditional Chinese
	Medicine Administration Project of Sichuan Province (No. 2012-E-063);

Data Component	Data Item
Literature Information	• Luo et al. 2019b <sup>22</sup>
Eligibility	• Selection or Exclusion: two inclusion criteria and six exclusion criteria
Methods	<ul> <li>Two-group comparison from a three-arm parallel randomized controlled trial</li> <li>Period of trial: seven weeks</li> <li>Period of follow-up: six months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: unclear</li> </ul>
Participants	<ul> <li>Sample size: 98</li> <li>Hand-ear acupuncture(n=54)</li> <li>Usual care groups (n=48)</li> </ul>
Interventions	<ul> <li>Number of intervention groups: one (out of two)</li> <li>Method of intervention: <ul> <li>Patients were acupunctured at hand points</li> <li>Yaotongdian (EXUE 7) every other day for four weeks followed by twice a week for three weeks, and at auricular points Yaotongdian (AH 9) in seven consecutive days followed by three-day intervals for seven weeks.</li> <li>All the acupoints were needled for 15 min, with needle stimulation by twirling the needles for 10 min and again at 10 min prior to removal.</li> </ul> </li> <li>Repeatability of intervention: high</li> </ul>
Outcomes	<ul><li>VAS</li><li>RMDQ</li><li>At baseline, two months and six months</li></ul>
Results	<ul> <li>VAS</li> <li>Baseline; 6.70 (6.14, 7.26) vs. 6.73 (6.17, 7.29)</li> <li>2 months; 3.85 (3.40, 4.31) vs. 5.92 (5.42, 6.41)</li> <li>6 months; 3.02 (2.49, 3.55) vs. 5.31 (4.85, 5,78)</li> <li>RMDQ</li> <li>Baseline; 12.15 (10.36, 13.93) vs. 13.50 (11.49, 11.49)</li> </ul>

# **Table 4.** Data Items Extracted From the Selected Literature (cont.)

	<ul> <li>15,51)</li> <li>2 months; 6.46 (5.42, 7.50) vs. 12.31 (10.30, 14.32)</li> <li>6 months; 4.41 (3.22, 5.59) vs. 11.75 (9.92, 13.58)</li> </ul>
Others	<ul> <li>Sponsor of research fund; Traditional Chinese Medicine Administration Project of Sichuan Province (No. 2012-E-063)</li> </ul>

Data Component	Data Item				
Literature Information	• Inoue et al. 2009 <sup>26</sup>				
Eligibility	• Selection or exclusion: Patients suspected of having coexisting low back pain due to reasons other than musculoskeletal disorders, and patients who had received other treatment for low back pain within one month of the start of the trial were excluded.				
Methods	<ul> <li>A two-arm parallel randomized controlled trial with acupuncture and local anesthetic injection</li> <li>Frequency and Period of trial: once a week for four weeks of treatment.</li> <li>Period of follow-up: four weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: High</li> <li>Blinding: unclear</li> </ul>				
Participants	<ul> <li>Sample size: 26</li> <li>Experimental group (n=13)</li> <li>Control group (n=13)</li> </ul>				
Interventions	Number of intervention groups: one Method of intervention: two-to-five of the most tender points, Ashi points. Repeatability of intervention: high Integrity of intervention: high				
Outcomes	<ul><li>VAS</li><li>At baseline, two weeks and four weeks after treatment</li></ul>				
Results	<ul> <li>VAS</li> <li>Baseline; 61.3±19.0 vs. 60.8±13.8</li> <li>4 weeks; 9.5±17.1 vs. 38.5±34.8</li> </ul>				
Others	• Sponsor of research fund; N/A				

Data Component     Data Item					
Literature Information	• Glazov et al. 2013a <sup>23</sup>				
Eligibility	• Selection or Exclusion: five inclusion criteria and seven exclusion criteria				
Methods	<ul> <li>Two-group comparison from a three-arm parallel randomized controlled trials with low-dose laser acupuncture and sham acupuncture</li> <li>Frequency and period of trial: six times per week, total of three weeks of treatment.</li> <li>Period of follow-up: 12 months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: high</li> </ul>				
Participants	<ul> <li>Sample size: 96</li> <li>Experimental group (n=48)</li> <li>Control group (n=48)</li> </ul>				
Interventions	<ul> <li>Number of intervention groups: one (out of two)</li> <li>Method of intervention: low dose: laser "on" with 10s (0.2 J) stimulation given per point. Average of about nine points in the Governing Vessel meridian, Bladder meridian, Gall Bladder meridian, extraordinary points and Ashi points</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>				
Outcomes	<ul> <li>Numerical Pain Rating Scale (NPRS)</li> <li>ODI</li> <li>At six weeks post-treatment</li> <li>Other outcomes: Secondary outcomes included a numerical rating scale for limitation of activity, global assessment of improvement, analgesic usage, and adverse effects after treatment</li> </ul>				
Results	<ul> <li>Mean change</li> <li>NPRS; -1.3 (-0.8, -2.0) vs1.5 (-0.8, -2.1)</li> <li>ODI; -4.1(-1.5, -6.7) vs4.0 (-1.0, -7.1)</li> </ul>				
Others	<ul> <li>Sponsor of research fund: Commonwealth Government of Australia</li> </ul>				

Data Component	Data Item				
Literature Information	• Glazov et al. 2013b <sup>23</sup>				
Eligibility	• Selection or Exclusion: five inclusion criteria and seven exclusion criteria				
Methods	<ul> <li>Two-group comparison from a three-arm parallel randomized controlled trial with high-dose laser acupuncture and sham acupuncture</li> <li>Frequency and period of trial: six times per week, total of three weeks of treatment.</li> <li>Period of follow-up: 12 months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: high</li> </ul>				
Participants	<ul> <li>Sample size: 96</li> <li>Experimental group (n=48)</li> <li>Control group (n=48)</li> </ul>				
Interventions	<ul> <li>Number of intervention groups: one (out of two)</li> <li>Method of intervention: High dose: laser "on" with 40s (0.8 J) stimulation given per point. Average of about nine points in the Governing Vessel meridian, Bladder meridian, Gall Bladder meridian, extraordinary points and Ashi points</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>				
Outcomes	<ul> <li>NPRS</li> <li>ODI</li> <li>At six weeks post-treatment</li> <li>Other outcomes: Secondary outcomes included a numerical rating scale for limitation of activity, global assessment of improvement, analgesic usage, and adverse effects after treatment</li> </ul>				
Results	<ul> <li>Mean change</li> <li>NPRS: -1.1 (-0.5, -1.7) vs1.5 (-0.8, -2.1)</li> <li>ODI: -2.6 (-0.5, -5.7) vs4.0 (-1.0, -7.1)</li> </ul>				
Others	<ul> <li>Sponsor of research fund: Commonwealth Government of Australia</li> </ul>				

Data Component	Data Item				
Literature Information	Shankar et al. 2011 <sup>24</sup>				
Eligibility	• Selection or Exclusion: patients aged 30-50 years old, of				
	both sexes, with a history of moderate to severe intensity, non-radiating low back pain of six months or longer				
	duration, without apparent neurological deficit or any				
	prior history of acupuncture therapy were selected.				
Methods	• A three-arm parallel randomized controlled trial				
	• Frequency and period of trial: 10 sittings delivered on alternate days				
	• Period of follow-up: three weeks				
	Order of randomization: high				
	Concealment of randomization order: unclear				
<u> </u>	Blinding: unclear				
Participants	• Sample size: 60				
	• Experimental group (n=30)				
<b>T</b>	Conventional therapy group (n=30)				
Interventions	• Number of intervention groups: one				
	• Method of intervention: electro acupuncture on UB 23, 24,				
	36, 37, 40, 57, 60, GB 30, 34 and GV 4 (The needles were stimulated electrically from a bottery powered electro				
	stimulated electrically from a battery-powered electro stimulator providing a rectangular wave pulse and a				
	current of 0.5 mA; an output of 06-9 volts was delivered at				
	10-20 Hz for 20 min.)				
	<ul> <li>Repeatability of intervention: high</li> </ul>				
	Integrity of intervention: high				
Outcomes	• VAS				
	• Global perceived effect (GPE)				
	• At baseline, three weeks				
Results	• VAS				
	• Baseline: 6.80±1.33 vs. 6.90±1.45				
	• Three weeks: 3.30±1.58 vs. 5.30±0.74				
	• GPE				
	• Baseline: 2.03±0.65 vs. 2.00±0.45				
	• Three weeks: 5.50±0.68 vs. 5.30±0.74				
Others	• Sponsor of research fund: N/A				

Data Component	Data Item			
Literature Information	• Zaringhalam et al. 2010a <sup>25</sup>			
Eligibility	• Selection or exclusion: seven inclusion criteria and one exclusion criterion			
Methods	<ul> <li>Four-arm parallel randomized controlled trial</li> <li>Frequency and period of trial: two times per week,</li> <li>total of five weeks of treatment</li> <li>Period of follow-up: 10 weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: unclear</li> </ul>			
Participants	<ul> <li>Sample size: 42</li> <li>Experimental group (AC) (n=21)</li> <li>Control group (n=21)</li> </ul>			
Interventions	<ul> <li>Number of intervention groups: one out of three</li> <li>Method of intervention: each patient received acupuncture bilaterally in the following acupoints: Shenshu (BL 23), Dachangshu (BL 25), Panguanshu (BL 28), Ciliao (BL 32), Kunlun (BL 60), Huantiao (GB 30) and Yanglingquan (GB 34)</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>			
Outcomes	<ul><li>VAS</li><li>RMDQ</li><li>At baseline, five weeks</li></ul>			
Results	<ul> <li>VAS</li> <li>Baseline: 6.43±1.78 vs. 6.45±1.83</li> <li>Five weeks: 4.70± 1.91 vs. 6.43± 2.38</li> <li>RMDQ</li> <li>Baseline: 9.8± 4.2 vs. 9.7± 4.4</li> <li>Five weeks: 6.4 (2.9) vs. 9.8± (3.8)</li> </ul>			
Others	• Sponsor of research fund: N/A			

Data Component	Data Item				
Literature Information	• Zaringhalam et al. 2010b <sup>25</sup>				
Eligibility	• Selection or exclusion: seven inclusion criteria and one exclusion criteria				
Methods	<ul> <li>A four-arm parallel randomized controlled trial</li> <li>Frequency and period of trial: two times a week, total of five weeks of treatment.</li> <li>Period of follow-up: 10 weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: unclear</li> </ul>				
Participants	<ul> <li>Sample size: 42</li> <li>Experimental group (AC+BA) (n=21)</li> <li>Control group (n=21)</li> </ul>				
Interventions	<ul> <li>Number of intervention groups: one out of three</li> <li>Method of intervention: Each patient received acupuncture bilaterally in the following acupoints:</li> <li>Shenshu (BL 23), Dachangshu (BL 25), Panguanshu (BL 28), Ciliao (BL 32), Kunlun (BL 60), Huantiao (GB 30), Yanglingquan (GB 34), and 30 mg/day (15 mg bid) of baclofen per oral.</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>				
Outcomes	<ul><li>VAS</li><li>RMDQ</li><li>At baseline, five weeks</li></ul>				
Results	<ul> <li>VAS</li> <li>Baseline: 6.46±1.68 vs. 6.45±1.83</li> <li>Five weeks: 4.01± 1.33 vs. 6.43± 2.38</li> <li>RMDQ</li> <li>Baseline: 9.5± 2.8 vs. 9.7± 4.4</li> <li>Five weeks: 5.7±1.4 vs. 9.8± 3.9</li> </ul>				
Others	• Sponsor of research fund: N/A				

Data Component	Data Item		
Literature Information	• Zaringhalam et al. 2010c <sup>25</sup>		
Eligibility	• Selection or exclusion: seven inclusion criteria and one exclusion criteria		
Methods	• A four-arm parallel randomized controlled trial		
	• Frequency and period of trial: two times a week, total of five weeks of treatment.		
	• Period of follow-up: 10 weeks		
	• Order of randomization: high		
	• Concealment of randomization order: high		
	Blinding: unclear		
Participants	• Sample size: 42		
	• Experimental group (AC+BA) (n=21)		
	• Control group (BA)(n=21)		
Interventions	• Number of intervention groups: one out of three		
	• Method of intervention: Each patient received		
	acupuncture bilaterally in the following acupoints:		
	Shenshu(BL 23), Dachangshu (BL 25), Panguanshu (BL 28), Ciliaa (BL 22), Kunlun (BL 60), Huantiaa (CP 20)		
	28), Ciliao (BL 32), Kunlun (BL 60), Huantiao (GB 30), and Yanglingquan (GB 34).		
	<ul> <li>30 mg/day (15 mg bid) of baclofen per oral for each group</li> </ul>		
	• Repeatability of intervention: high		
	• Integrity of intervention: high		
Outcomes	• VAS		
	• RMDQ		
	• At baseline, five weeks		
Results	• VAS		
	• Baseline; 6.46±1.68 vs. 6.45±1.83		
	• Five weeks; $4.01 \pm 1.33$ vs. $6.19 \pm 2.23$		
	• RMDQ		
	• Baseline; $9.5\pm 2.8$ vs. $9.8\pm 4.2$		
	• 5 weeks; 5.7±1.4 vs. 8.8± 3.8		
Others	• Sponsor of research fund: N/A		

Data Component	Data Item			
Literature Information	• Cherkin et al. 2009a <sup>27</sup>			
Eligibility	• Selection or exclusion: inclusion criteria-persons with diagnosis codes consistent with uncomplicated chronic low back pain within the prior 3 to 12 months, and five exclusion criteria			
Methods	<ul> <li>A four-arm parallel randomized controlled trial</li> <li>Frequency and period of trial: two times a week for three weeks and then once per week for four weeks.</li> <li>Period of follow-up: 52 weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: high</li> </ul>			
Participants	<ul> <li>Sample size: 300</li> <li>Experimental group (n=152, 6 drop-off and others)</li> <li>usual care group (n=148, 13 drop-off and others)</li> </ul>			
Interventions	<ul> <li>Number of intervention groups: one out of two</li> <li>Method of intervention: standardized Acupuncture; Du 3, Bladder 23-bilateral, low back ashi point, Bladder 40- bilateral, Kidney 3-bilateral</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>			
Outcomes	<ul> <li>RMDQ</li> <li>Bothersomeness scale</li> <li>At baseline, eight weeks</li> </ul>			
Results	<ul> <li>RMDQ</li> <li>Baseline: 10.8±5.5 vs. 11.0±5.1</li> <li>Eight weeks: 6.3±5.7 vs. 8.9±6.0</li> <li>Bothersomeness scale</li> <li>Baseline: 5.0±2.3 vs. 5.4±2.3</li> <li>Eight weeks: 3,3±2.5 vs. 4.7±2.6</li> </ul>			
Others	<ul> <li>Sponsor of research fund: National Institutes of Health (NIH) Cooperative Agreement (U01 AT 001110) with the National Center for Complementary and Alternative Medicine (NCCAM).</li> </ul>			

Data Component	Data Item			
Literature Information	• Cherkin et al. 2009b <sup>27</sup>			
Eligibility	• Selection or exclusion: inclusion criteria-persons with diagnosis codes consistent with uncomplicated chronic low back pain within the prior 3 to 12 months, and five exclusion criteria			
Methods	<ul> <li>A four-arm parallel randomized controlled trial</li> <li>Frequency and period of trial: two times per week for three weeks and then once per week for four weeks</li> <li>Period of follow-up: 52 weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: high</li> </ul>			
Participants	<ul> <li>Sample size: 300</li> <li>Experimental group (Individualized Acupuncture group) (n=157, 25 drop-off and others)</li> <li>Usual care group (n=148, 13 drop-off and others)</li> </ul>			
Interventions	<ul> <li>Number of intervention groups: one out of two</li> <li>Method of intervention: Individualized Acupuncture; Treatments averaged 10.8 needles, half on the "Bladder Meridian"</li> <li>Repeatability of intervention: unclear</li> <li>Integrity of intervention: high</li> </ul>			
Outcomes	<ul> <li>RMDQ</li> <li>Bothersomeness scale</li> <li>At baseline, eight weeks</li> </ul>			
Results	<ul> <li>RMDQ</li> <li>Baseline: 10.8±5.2 vs. 11.0±5.1</li> <li>Eight weeks: 6.4±5.3 vs. 8.9±6.0</li> <li>Bothersomeness scale</li> <li>Baseline: 5.0±2.5 vs. 5.4±2.3</li> <li>Eight weeks: 3.4±2.7 vs. 4.7±2.6</li> </ul>			
Others	<ul> <li>Sponsor of research fund: National Institutes of Health (NIH) Cooperative Agreement (U01 AT 001110) with the National Center for Complementary and Alternative Medicine (NCCAM)</li> </ul>			

Table 4.	Data	Items	Extracted	From	the	Selected	Literature	(cont.)	)
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Data Component     Data Item			
Literature information	• Hakke et al. 2007 <sup>28</sup>		
Eligibility	• Selection or Exclusion: 6 inclusion criteria and 13 exclusion criteria		
Methods	<ul> <li>Two group comparison from a three-arm parallel randomized controlled trial with verum acupuncture and sham acupuncture</li> <li>Frequency and period of trial: two sessions per week, up to fifteen sessions of treatment</li> <li>Period of follow-up: six months</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: high</li> <li>Blinding: high</li> </ul>		
Participants	<ul> <li>Sample size: 774</li> <li>Experimental group (n=387)</li> <li>Control group (n=387)</li> </ul>		
Interventions	<ul> <li>Number of intervention groups: one</li> <li>Method of intervention: 14-20 needles consisted of fixed points and additional points from a prescribed list</li> <li>Repeatability of intervention: high</li> <li>Integrity of intervention: high</li> </ul>		
Outcomes	<ul> <li>Von Korff Chronic Pain Grade Scale (CPGS)</li> <li>Hanover Functional Ability Questionnaire (HFAQ)</li> <li>At baseline, six weeks, three months and six months after treatment</li> <li>Other outcome measures; Short Form Health Survey, global patient assessment of therapy effectiveness</li> </ul>		
Results	<ul> <li>CPGS</li> <li>Baseline: 67.7 ± 13.9 (387) vs. 67.8 ± 13.2 (387)</li> <li>Six weeks: 48.6 ± 18.5 (370) vs. 51.0 ± 18.7 (375)</li> <li>Three months: 45.4 ± 19.4 (373) vs. 48.5 ± 19.5 (376)</li> <li>Six months: 40.2 ± 22.5 (377) vs. 43.3 ± 23.0</li> </ul>		

	(376)
	• Success: 229 (59.2%) vs. 197 (50.9%)
	• HFAQ (disability)
	<ul> <li>Baseline: 46.3 ± 14.7 (387) vs. 46.3 ± 15.3 (387)</li> </ul>
	<ul> <li>Six weeks: 64.0 ± 21.1 (370) vs. 61.3 ± 20.8 (375)</li> </ul>
	• Three months: $65.4 \pm 22.9 (373)$ vs. $61.3 \pm 22.7 (376)$
	• Six months: $66.8 \pm 23.1 (377)$ vs. $62.2 \pm 23.0 (376)$
	• Success: 281 (72.6%) vs. 251 (64.9%)
Others	• Sponsor of research fund: German public health insurance companies

Data Component	Data Item
Literature Information	• Brinkhaus et al. 2006 <sup>29</sup>
Eligibility	• Selection or Exclusion: 5 inclusion criteria and 10 exclusion criteria
Methods	<ul> <li>A three-arm parallel randomized controlled trial</li> <li>Frequency and Period of trial: 12 sessions, total of eight weeks of treatment.</li> <li>Period of follow-up: 52 weeks</li> <li>Order of randomization: high</li> <li>Concealment of randomization order: unclear</li> <li>Blinding: high</li> </ul>
Participants	<ul> <li>Sample size: 214</li> <li>Experimental group (n=140, 7 drop-off and others)</li> <li>Waiting list group (n=74, 5 drop-off and others)</li> </ul>
Interventions	<ul> <li>Number of intervention groups: one</li> <li>Method of intervention: All patients were treated with a selection of local and distant points, including (bilaterally) at least four local points from the following selection: Bladder 20 to 34; Bladder 50 to 54; Gallbladder 30; Governing vessel 3,4,5 and 6; and extraordinary points Huatojiaji and Shiqizhuixia. Also, physicians selected at least two distant points(bilaterally) from the following sample: small intestine 3; bladder 40, 60, and 62; Kidney 3 and 7; Gall bladder 31, 34, and 41; Liver 3; and Governing vessel 14 and 20.</li> </ul>
Outcomes	• VAS
Results	<ul> <li>Change of mean VAS in eight weeks</li> <li>2.87±3.03 vs. 0.69±2.20</li> </ul>
Others	• Sponsor of research fund: German social health insurance companies.

#### **Risk of Bias Within the Included Studies**

Risk of Bias (RoB) in the 10 selected studies was assessed by using RoB software provided by RevMan 5.4 and the Cochrane Risk of Bias Assessment Tool, which comprises seven qualitative elements. The graph and summary of the methodological quality assessment based on the results are illustrated in Figures 2 and 3.

All of the studies conducted the randomization sequence using computer-generated random numbers or simple randomization methods. Concealment of randomization order was conducted in seven studies through sealed envelopes or central randomization, but was unclear in three studies. Four studies were deemed to use blinding, but the remaining studies did not provide sufficient information regarding blinding. All of the studies fulfilled the categories of incomplete outcome data and selective outcome.

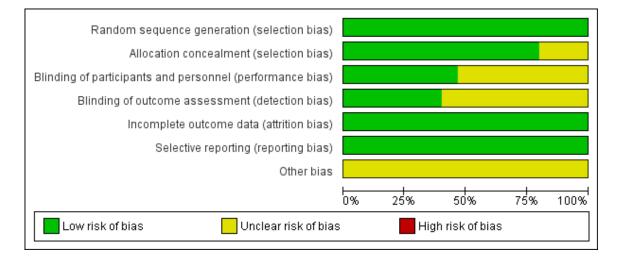


Figure 2. Risk of Bias Graph

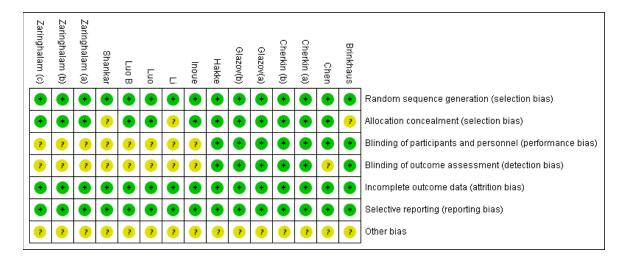


Figure 3. Risk of Bias Summary

#### **Meta-analyses of Outcomes**

The outcomes in the 15 randomized controlled trials were meta-analyzed using RevMan 5.4,

and forest plots show the results from individual studies and pooled analyses (Figures 4-7).

#### Visual Analog Scale (VAS) Score

The VAS score was improved in the acupuncture group compared to the control group, but with substantial heterogeneity. [MD 0.16 (0.11, 0.21), 95% CI, P < 0.0001]  $I^2 = 55$  % (Figure 4).

Experimental		al	Control				Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
Brinkhaus	0.287	0.303	140	0.069	0.22	74	18.1%	0.22 [0.15, 0.29]	+
Chen	0.418	0.127	64	0.354	0.13	62	20.9%	0.06 [0.02, 0.11]	•
Inoue	0.58	0.362	13	0.223	0.529	13	3.0%	0.36 [0.01, 0.71]	
Li	0.34	0.3	35	0.26	0.3	35	11.0%	0.08 [-0.06, 0.22]	+
Luo	0.152	0.43	50	0.08	0.792	48	5.0%	0.07 [-0.18, 0.33]	_ <del></del>
Luo B	0.285	0.372	54	0.081	0.365	48	10.8%	0.20 [0.06, 0.35]	
Shankar	0.35	0.292	30	0.16	0.23	30	11.6%	0.19 [0.06, 0.32]	
Zaringhalam (a)	0.173	0.3692	21	0.002	0.278	21	7.2%	0.17 [-0.03, 0.37]	+
Zaringhalam (b)	0.245	0.303	21	0.002	0.424	21	6.1%	0.24 [0.02, 0.47]	
Zaringhalam (c)	0.245	0.303	21	0.026	0.408	21	6.3%	0.22 [0.00, 0.44]	
Total (90% CI)			449			373	100.0%	0.16 [0.11, 0.21]	•
Heterogeneity: Tau <sup>2</sup> =	= 0.00; C	hi² = 20.0	)5, df =	9 (P = 0	).02); <b>I</b> ²÷	= 55%		ŀ	-2 -1 0 1 2
Test for overall effect: Z = 4.92 (P < 0.00001)									-2 -1 U 1 2 Favours [Control] Favours [Experimental]

Figure 4. Meta-Analysis of Visual Analog Scale

## Numeric Pain Rating Scale (NPRS)

The NPRS was lower in the acupuncture group compared to the control group, and the  $I^2$  value indicated that heterogeneity was not significant. [MD -0.31 (-0.92, 0.30), 90% CI, P = 0.32]  $I^2$ = 0% (Figure 5).

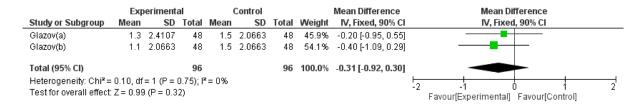


Figure 5. Meta-Analysis of Numeric Pain Scale

## **Roland Morris Disability Questionnaire (RMDQ)**

The RMDQ after acupuncture treatment was improved significantly over that after the

intervention in the control group with significant heterogeneity. [MD 0.60 (0.01, 1.18), 95% CI,

P=0.09]  $I^2$  =94% (Figure 6).

	Exp	eriment	al	C	ontrol			Mean Difference		Mea	n Differen	ce	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl		IV, Ra	ndom, 95	% CI	
Cherkin (a)	0.45	1.117	152	0.21	1.11	148	49.9%	0.24 [-0.01, 0.49]					
Cherkin (b)	1.16	1.04	157	0.21	1.11	148	50.1%	0.95 [0.71, 1.19]					
Total (90% CI)			309			296	<b>100.0</b> %	0.60 [0.01, 1.18]			•		
Heterogeneity: Tau <sup>2</sup> = 0.24; Chi <sup>2</sup> = 15.88, df = 1 (P < 0.0001); l <sup>2</sup> = 94% Test for overall effect: Z = 1.68 (P = 0.09)										-2 Usual c	0 are Stan	2 dard acu	4 puncture

Figure 6. Meta-Analysis of Roland Morris Disability Questionnaire

#### **Chronic Pain Grade Scale (CPGS)**

The CPGS was lower in the acupuncture group compared to the control group. [MD 0.02 (-0.03, 0.07), 95%CI, P=0.48]. Heterogeneity: N/A due to only one randomized controlled trial (Figure 7).

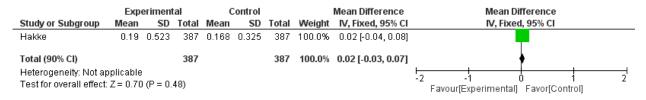


Figure 7. Meta-Analysis of Chronic Pain Grade Scale

## **Identification of Reporting Bias**

Identification of the reporting bias was performed on 10 randomized controlled trials in terms of VAS using a funnel plot (Figure 8). The funnel plot showed symmetry in the upper part, which might be the studies that have followed all processes systematically. However, the result items in the lower part appeared an asymmetry that might be due to the small number of studies and a potential publication bias.

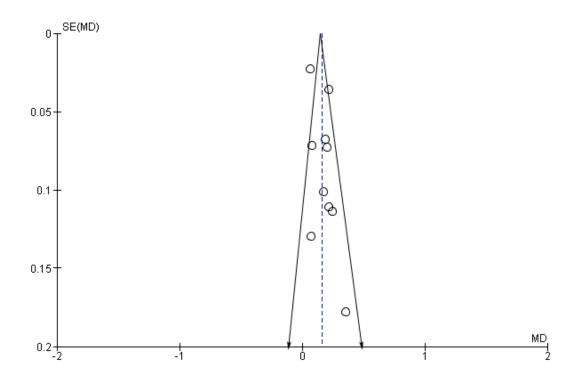


Figure 8. Funnel Plot of the included studies in terms of VAS

#### Safety

## Adverse Effects

Brinkhaus (2006) reported 27 adverse effects are related to study treatment, including 15 patients who received acupuncture and 12 patients who received minimal acupuncture. The most frequently reported adverse effects were hematoma and bleeding. Hakke (2007) reported that, during the six months, 40 serious adverse events were documented: 12 each in the verum and sham acupuncture groups and 16 in the conventional therapy group. All were deemed unrelated to the intervention, and the number of serious adverse events corresponds to the statistically expected frequency.

Cherkin (2009) reported 11 cases of short-term pain, one with a severe experience (pain lasting one month), one with dizziness, and one with back spasms. Glazov (2014) reported a flare-up of back pain in the week following 28% of treatments and some other adverse effects after 25% of

treatments; however, there was no significant difference in the frequency of flare pain or other adverse effects between treatment groups. Luo (2019) reported one case of needling pain in the hand-ear treatment group and one with anxiety in the standard acupuncture group. Chen 2022 reported that in the observation group, three patients experienced acupuncture fainting, all of which were caused by receiving treatment on an empty stomach; two patients had mild skin buns, which were caused by improper technique by the operator, and all of them could continue the treatment after symptomatic treatment.

#### **IV. DISCUSSION**

Low back pain may be the most prevalent illness, with many individuals experiencing it at least once in their lifetimes, and it remains a significant global public health concern. LBP can result from wide-ranging injuries, conditions, and diseases. Low back muscle spasms and muscle blood flow decrease can cause chronic LBP.<sup>30</sup> Pain medications, muscle relaxants, physical therapy, steroid medications, cortisone injections, and hands-on treatments have all been used for low back pain relief, and some back conditions require surgical repair. Medications and surgery may be helpful for patients with LBP, but for long-term treatment, they should be used cautiously due to the risk of serious side effects. Meanwhile, acupuncture has provided pain relief and manifested a functional improvement as a treatment for LBP.

In Oriental medicine (OM), LBP can be caused by the stagnation or deficiency of qi and blood or invasion of cold-dampness, or deficiency in kidney Yin or Yang. Treatment for LBP in OM focuses on promoting the circulation of qi and blood, dispelling cold dampness, removing obstruction in meridians, tonifying qi, and nourishing blood.

Acupuncture alleviates tension and improves blood flow in the treated muscles,<sup>31</sup> and acupuncture treatment may improve lumbar function and reduce pain by increasing blood flow to the affected region.<sup>32</sup>

According to an article in *Harvard Health* (2016), acupuncture may relieve pain by releasing endorphins, the body's natural pain-killing chemicals, and by affecting the part of the brain that governs serotonin, a brain chemical involved with mood.<sup>33</sup> Another review of the effectiveness of acupuncture in treating pain concluded that acupuncture enhances the descending inhibitory effect and modulates the feeling of pain, thereby modifying central sensitization.<sup>34</sup> Moreover, acupuncture can reduce the levels of inflammatory mediators locally.<sup>34</sup> Also, one clinical trials has

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demonstrated that, after acupuncture for 15 and 45 minutes, cortisol increase was 28 and 50%, respectively.<sup>35</sup>

There is a growing number of articles regarding the benefits and effectiveness of acupuncture in treating pain. Acupuncture has been used widely by patients with LBP, and acupuncture treatment has resulted in clinically significant improvement among patients. Nevertheless, its effectiveness in pain reduction still lacks evidence. The views concerning the efficacy of acupuncture treatment are usually contradictory, and it is difficult to explain the nature of philosophical phenomenon using scientific methods.<sup>22</sup>

In this meta-analysis, the results indicate that acupuncture treatment is effective in reducing pain compared to other therapies. However, there are limitations to interpreting results in this review due to the small sample size, and many of the randomized controlled trials in the included studies had unclear RoB. Not all studies reported adverse effects that indicate the safety of treatment.

#### **V. CONCLUSION**

The meta-analysis result in the included studies showed that acupuncture treatment was associated with improvements in VAS score [MD 0.16 (0.11, 0.21), 95% CI, P < 0.0001]  $I_2 = 55\%$ , NPRS [MD -0.31 (-0.92, 0.30), 90% CI, P = 0.32]  $I_2 = 0\%$ , RMDQ [MD 0.60 (0.01, 1.18), 95% CI, P = 0.09]  $I_2 = 94\%$ , and CPGS [MD 0.02 (-0.03, 0.07), 95% CI, P=0.48] in patients with low back pain. Accordingly, this systematic review and meta-analysis demonstrated the effects, benefits, and safety of acupuncture treatment over other therapies for pain relief. However, scientific evidence as to the effectiveness of acupuncture in treating LBP compared to other treatments remains insufficient. Furthermore, ongoing research and randomized controlled trials with high-quality, larger sample sizes and rigorous trial designs are needed to demonstrate the effectiveness of acupuncture in treating LBP. There needs to be improved future clinical trials and in-depth investigation on adverse effects to obtain accurate results. Finally, regarding clinical trials, standardizing outcomes and durations of acupuncture sessions, including rigorous assessment for RoB, are needed.

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## Appendix I

**Q** Statistics

$$Q = \sum_{k}^{i=1} W_i Y_i^2 - \frac{(\sum_{k}^{i=1} W_i Y_i)^2}{\sum_{k}^{i=1} W_i} \qquad Q = \sum_{k}^{i=1} W_i (Y_i - M)^2$$

# Higgin's I<sup>2</sup> Statistics

$$I^2 = \frac{Q - df}{Q} \times 100\%$$

(Q:Q statistics, df: degree of freedom)

## The Weighted Average in the Random-effects Model

$$WMD_{summary} = \frac{weight_i \times mean_i}{weight_i}$$

$$weight_i = \frac{1}{variance_i} = \frac{1}{SD^2}$$

 $variance_{S} = \frac{1}{\sum weight_{i}}$ 

## Standardized Mean Difference (SMD) for Random Effects Model

$$SMD_{summary} = \frac{weight_i \times SMD_i}{weight_i}.$$

$$SMD_i = \frac{Difference in mean outcome between groups}{Standard deviation of outcome among participants}.$$

Cohen's *d* Value

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s}.$$

## Appendix II

## Visual Analog Scale (VAS)

The visual analog scale for pain is a straight line, with one end indicating no pain and the other

end signifying the worst pain imaginable. A patient marks a point on the line that matches the

amount of pain he or she feels.<sup>36</sup>

## Pre And Post-Treatment Visula Analogue Sclae By American Specialty Health, Outcome

Assessment Tools and Instruction, Ver 12.0, 2012

## PRE-TREATMENT VAS

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain \_\_\_\_\_ Unbearable

FOLD HERE------

POST-TREATMENT VAS (fold in half when completing post-test VAS)

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

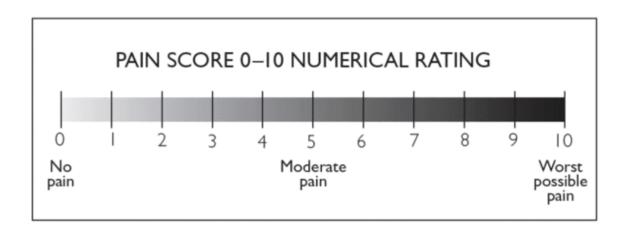
No Pain \_\_\_\_\_ Unbearable

#### Numeric Pain Rating Scale (NPRS)<sup>37</sup>

The NPRS is a segmented numeric version of the visual analog scale (VAS) in which a

respondent selects a whole number (0-10) that best reflects the intensity of pain.

- The common format is a horizontal bar or line.
- Similar to the VAS, the NPRS is anchored by terms describing pain severity extremes.
- The 11-point numeric scale ranges from "0," representing one pain extreme (i.e., "no pain") to "10" representing the other pain extreme (i.e., "pain as bad as you can imagine" or "worst pain imaginable").
- The NPRS can be administered verbally (including by telephone) or graphically for self-completion. The respondent is asked to indicate the numeric value on the segmented scale that best describes their pain intensity.



## Roland-Morris Disability Questionnaire (RMDQ)<sup>38</sup>

The Roland-Morris Disability Questionnaire follows the progress of a patient's functional improvement with low back pain over time. Every 1-2 weeks, the patient is asked to fill out the questionnaire. The patient checks each applicable statement (24 total) on that day. The total number of checks is recorded and followed over time to track the patient's functional progress. The RMDQ is shown below.

# Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

## Instructions

Pat	tient name: F	ile #:	Date:						
	ase read instructions: When your back hurts, you may find mally do. Mark only the sentences that describe you today		do some of the things you						
	I stay at home most of the time because of my back.								
	I change position frequently to try to get my back comfortable.								
	I walk more slowly than usual because of my back.								
	Because of my back, I am not doing any jobs that I usually do around the house.								
	Because of my back, I use a handrail to get upstairs.								
	Because of my back, I lie down to rest more often.								
	Because of my back, I have to hold on to something to get out of an easy chair.								
	Because of my back, I try to get other people to do thing	gs for me.							
	I get dressed more slowly than usual because of my back.								
	I only stand up for short periods of time because of my back.								
	Because of my back, I try not to bend or kneel down.								
	I find it difficult to get out of a chair because of my back.								
	My back is painful almost all of the time.								
	I find it difficult to turn over in bed because of my back.								
	My appetite is not very good because of my back.								
	I have trouble putting on my socks (or stockings) because of the pain in my back.								
	I can only walk short distances because of my back pair	n.							
	I sleep less well because of my back.								
	Because of my back pain, I get dressed with the help of someone else.								
	I sit down for most of the day because of my back.								
	I avoid heavy jobs around the house because of my back.								
	Because of back pain, I am more irritable and bad tempered with people than usual.								
	Because of my back, I go upstairs more slowly than usu	ial.							
	I stay in bed most of the time because of my back.								

## Chronic Pain Grade Scale (CPGS)<sup>39</sup>

CPGS is a questionnaire for grading pain and multidimensional measure that assesses two dimensions of overall chronic pain severity: pain intensity and pain-related disability. The CPGS includes seven items as follows:

- 1. How would you rate your pain on a 0-10 scale at the present time, this is right now, where 0 is "no pain" and 10 is "pain as bad as it could be"?
- 2. In the past six months, how intense was your worse pain rated on a 0-10 scale (rated as above)?
- 3. In the past six months, on average, how intense was your pain rated on a 0-10 scale (rated as above)? (That is your usual pain at times you were experiencing pain.)
- 4. About how many days in the last six months have you been kept from your usual activities (work, school, housework) because of this pain?
- 5. In the past six months, how much has this pain interfered with your daily activities on a 0-10 scale where 0 is "no interference" and 10 is "extreme change"?
- 6. In the past six months, how much has this pain changed your ability to take part in recreational, social, and family activities where 0 is "no change" and 10 is "extreme change"?
- 7. In the past six months, how has this pain changed your ability to work (including housework) where 0 is "no change" and 10 is "extreme change"?