

## Postprint: Current Status Analysis of Outcome Measures in Randomized Controlled Trials of Acupuncture for Chronic Nonspecific Low Back Pain

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### Abstract

**Objective:** To evaluate the current status of outcome measure selection in randomized controlled trials (RCTs) of acupuncture for chronic non-specific low back pain, and to provide a basis for related research on acupuncture treatment of chronic non-specific low back pain. **Methods:** Four Chinese databases (CNKI, VIP, Wanfang, CBM) and three English databases (PubMed, EmBase, Cochrane Library) were systematically searched. Randomized controlled trials of acupuncture for chronic non-specific low back pain were selected according to pre-established inclusion criteria. A total of 2743 relevant articles were initially retrieved, and 49 randomized controlled trials were finally included. Concurrently, existing Core Outcome Sets (COS) for chronic non-specific low back pain were summarized and compared with the outcome measures used in current acupuncture trials for chronic non-specific low back pain. **Results:** The outcome measures of the 49 RCTs were mainly categorized into 10 types: pain measures, functional disability measures, composite measures, quality of life measures, activities of daily living measures, safety measures, patient satisfaction measures, disease perception measures, psychological status measures, and other measures. Compared with existing COS, all showed varying degrees of attention to outcomes related to pain, functional disability, quality of life, psychological status, and patient satisfaction, but there were substantial differences in measure selection among different COS and among different acupuncture RCTs. **Conclusion:** There are some differences and existing problems between the outcome measures in RCTs of acupuncture for chronic non-specific low back pain and current COS. It is recommended that future acupuncture studies refer to existing COS and commonly used measurement instruments when designing outcome measures, while also expanding corresponding recognized outcome measures based on the

characteristics of the research itself.

## Full Text

### Preamble

**Title:** Analysis of the Current Status of Outcome Measures in Randomized Controlled Trials of Acupuncture for Chronic Nonspecific Low Back Pain

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## Abstract

**Objective:** To evaluate the outcome measures selected in randomized controlled trials (RCTs) of acupuncture for chronic nonspecific low back pain (CNSLBP) and to provide a basis for related acupuncture research.

**Methods:** Four Chinese databases (CNKI, VIP, Wanfang, CBM) and three English databases (PubMed, EMBASE, Cochrane Library) were systematically searched. RCTs of acupuncture for CNSLBP were selected according to predetermined criteria. A total of 2,743 relevant studies were initially retrieved, with 49 RCTs ultimately included. Existing core outcome sets (COS) for chronic nonspecific low back pain were summarized and compared with the outcome measures used in the included acupuncture RCTs.

**Results:** The outcome measures from the 49 RCTs were classified into 10 categories: pain measures, functional disability measures, composite measures, quality of life measures, activities of daily living measures, safety measures, patient satisfaction measures, disease cognition measures, psychological status measures, and other measures. Compared with existing COS, all showed varying degrees of attention to pain, functional disability, quality of life, psychological status, and patient satisfaction. However, substantial differences existed in measure selection both across different COS and across different acupuncture RCTs.

**Conclusion:** Outcome measures in acupuncture RCTs for CNSLBP show some differences from existing COS and have several problems. Future acupuncture studies should refer to established COS and commonly used measurement tools

when designing outcome measures, while expanding with appropriate recognized outcome measures based on the specific characteristics of the study.

**Keywords:** acupuncture; chronic nonspecific low back pain; randomized controlled trial; Core Outcome Set; outcome measures

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## Introduction

Nonspecific low back pain (NSLBP) refers to a common condition characterized by subjective pain in the lower back, lumbosacral region, sacroiliac area, buttocks, or legs without a clear etiology, excluding specific spinal diseases and radicular pain [1]. Approximately 90-95% of low back pain patients have nonspecific low back pain [2], with a reported global prevalence of 18% [3], making it the leading cause of disability among older adults [4].

Among 46 previously published guidelines for treating low back pain both domestically and internationally, 27 mention acupuncture therapy, with 16 recommending its application for low back pain [5]. Although randomized controlled trials (RCTs) are widely considered the gold standard for evaluating clinical efficacy [6], the selection of outcome measures in many current RCTs suffers from issues of scientific validity, applicability, and standardization, affecting sample size, study duration, costs, implementation, and the practical value and reusability of results [7], thereby hindering the translation of findings into valuable clinical evidence [8][9].

This study screened and analyzed the selection of outcome measures in RCTs of acupuncture for chronic nonspecific low back pain (disease course >12 weeks) published in the past five years, compared them with existing domestic and international COS for nonspecific low back pain, and analyzed existing problems to provide a basis for future clinical research design.

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### 1.1.1 Inclusion Criteria

- (1) Study design: RCT
- (2) Participants: Patients with chronic nonspecific low back pain with clear diagnostic criteria
- (3) Interventions: Acupuncture (including manual acupuncture or electroacupuncture) or combined acupuncture therapy (two or three of the following: acupuncture/electroacupuncture, moxibustion, cupping, with acupuncture/electroacupuncture required)
- (4) Outcomes: At least one outcome measure reported

### 1.1.2 Exclusion Criteria

- (1) Studies where acupuncture was combined with other treatments as the intervention
- (2) Duplicate publications
- (3) Dissertations (master' s or doctoral theses)
- (4) Studies where full text was unavailable

### 1.2 Search Strategy

Electronic databases searched: CNKI, Wanfang, SinoMed (CBM), VIP, PubMed, Embase, and Cochrane Library. The search period was from January 1, 2017 to March 15, 2022.

Chinese databases were searched using combinations of title, keywords, and subject terms with the following search terms: “low back pain,” “chronic low back pain,” “nonspecific low back pain,” “chronic nonspecific low back pain,” “lumbar muscle strain,” “third lumbar transverse process syndrome,” “lumbar myofasciitis,” “gluteal myofasciitis,” “lumbar sprain” ; “acupuncture,” “needle insertion,” “needling technique,” “filiform needle,” “electroacupuncture,” “body acupuncture,” “manual acupuncture” ; “moxibustion,” “moxibustion technique,” “moxa stick moxibustion,” “indirect moxibustion,” “sparrow-pecking moxibustion” ; “cupping,” “moving cupping,” “cupping technique,” “flash cupping.”

English databases were searched using MeSH terms combined with free text terms: Low Back Pain, Lower Back Pain, Low Back Ache, Postural Low Back Pain, Recurrent Low Back Pain, Mechanical Low Back Pain, Lumbago, lumbodinia, lumbar pain, osphyalgia, lumbar myalgia, lumbar sprain, lumbosacral sprain, lumbosacral strain, sacroiliac sprain, sacroiliac strain, muscular strain of the lumbar region, third lumbar transverse process syndrome, lumbar muscle fasciitis, lumbar gluteal myofasciitis, NLBP, CNLBP, NSLBP, CNSLBP; acupuncture, electroacupuncture, electro acupuncture, body acupuncture, body needling, body needle, hand acupuncture, manual needling, hand needle, manual acupuncture, acupuncture point, acupoint; moxibustion, moxacone moxibustion, indirect moxibustion, moxa stick moxibustion; cupping therapy, cupping treatment, cup moving, flash cupping, flash tank.

The PubMed search strategy is shown in Table 1 .

Two researchers independently conducted literature searching, screening, and data extraction. Two team members independently reviewed titles and abstracts for initial screening, then reviewed full texts for secondary screening. Data were extracted using Excel 2019, including: literature source, language, sample size, baseline demographic characteristics, disease duration, interventions, treatment course, outcome measures, follow-up, and adverse events. Uncertainties dur-

ing literature selection and data extraction were resolved through discussion between the two researchers, with a third reviewer consulted in case of disagreement. Finally, outcome measures from included studies were summarized and described.

#### 1.4 Data Analysis Methods

The classification of outcome measures, proportion of each category, and related efficacy criteria were described for RCTs of acupuncture for NSLBP from the seven databases between January 1, 2017 and March 15, 2022. Trends and application characteristics of outcome evaluation in acupuncture for NSLBP were analyzed.

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## Results

### 2.1 Literature Screening

A total of 2,743 studies were initially retrieved and imported into EndNote X9. After automatic and manual deduplication, 1,456 studies remained. After reading titles and abstracts, 496 studies were preliminarily selected. After reading full texts, 49 studies were ultimately included. The literature screening process and results are shown in Figure 1 [Figure 1: see original paper].

### 2.2 Basic Characteristics of Included Studies

All 49 included studies [10-58] were RCTs, including 4 English studies [17-19,37] and 45 Chinese studies [10-16,20-36,38-58]. Sample sizes ranged from 20 to 90 cases, with a mean sample size of 87 cases. A total of 4,272 patients were included, with 2,049 in the treatment group and 2,223 in the control group, aged 18-69 years. Thirty-eight studies [11-17,20-24,26-28,30-34,36,37,39-46,48-52,54-56] reported disease duration, which ranged from 30 days to 10 years when reported in units of days, weeks, months, or years. Thirty-six studies [10,11,13,16,17,19,20,23,24,26,28-44,48,49,51-57] used simple acupuncture, 9 studies [14,15,18,21,22,25,45,47,58] used electroacupuncture, 1 study [50] used warm acupuncture, 1 study [27] used acupuncture combined with cupping, 1 study [46] used electroacupuncture combined with cupping, and 1 study [12] used warm acupuncture combined with cupping. Treatment courses ranged from 3 days to 3 months. Two studies [27,58] did not mention treatment duration; 6 studies [10,30,35,42,47,57] had treatment courses within 1 week; 38 studies [11-18,20-29,31-34,36-41,44-46,48-53,55,56] had courses between 1 and 4 weeks; and 3 studies [19,43,54] had courses longer than 4 weeks. Ten studies [18,19,25,27,33,38,41,42,45,48] conducted follow-up, with 1 study [25] not mentioning follow-up duration and 9 studies [18,19,25,27,38,41,42,45,48] providing complete follow-up data ranging from 2 weeks to 6 months. Seven studies [12,17,18,19,37,38,50] reported adverse events, including 3 Chinese studies and

4 English studies. Basic characteristics and outcome measure evaluation details of the included literature are provided in Annex 1.

### 2.3.1 Outcome Domains

The 49 included RCTs used 33 different outcome measures, which were classified according to their evaluation content into: pain measures, functional disability measures, composite measures, quality of life measures, activities of daily living measures, safety measures, patient satisfaction measures, disease cognition measures, psychological status measures, and other measures. Pain measures directly or indirectly evaluate pain. Functional disability measures directly or indirectly evaluate the degree of lumbar functional limitation and its impact on daily activities. Composite measures evaluate two or more dimensions. Quality of life measures assess physical function, psychological status, health perception, and disease-related symptoms. Activities of daily living measures evaluate the ability to perform necessary daily activities. Safety measures relate to adverse events. Patient satisfaction measures assess patient satisfaction with treatment. Disease cognition measures assess personal understanding of the disease. Psychological status measures assess personal psychological states. Other measures assess accompanying symptoms of low back pain in the original studies. Outcome measures from the included RCTs are provided in Annex Table 1. The outcome domains are shown in Table 2 .

The 49 RCTs used 1-8 outcome measures each. Except for 2 RCTs [18,19] that specified primary and secondary outcome measures, the importance ranking of measures was unclear in the remaining studies. However, Kizhakkeveettil A [19] designated both functional disability and quality of life measures as primary outcomes. The other 47 RCTs either listed multiple measures directly or used a single outcome measure. None of the 49 RCTs reported sample size calculation based on any specific outcome measure.

Treatment courses in the 49 RCTs ranged from 3 days to 3 months. Forty-two RCTs measured outcomes at two time points (pre- and post-treatment), while the remaining 7 RCTs measured outcomes at pre-treatment, during treatment, and post-treatment. The timing of outcome measurement varied considerably across the 49 RCTs.

Reports of adverse events in the included RCTs were brief. Only 2 RCTs [38,50] reported safety measures, only 1 RCT [21] addressed psychological status measures, and only 1 RCT [18] mentioned blinding of outcome assessors.

## 2.4 Current Status of Existing Nonspecific Low Back Pain Core Outcome Sets

Using search terms “chronic nonspecific low back pain,” “chronic back pain,” “core outcome set,” and “core measurement set” in CNKI, Wanfang, CBM, VIP, PubMed, Embase, and Cochrane Library, 11 articles were retrieved (9 English, 2 Chinese).

COS is defined as a minimum set of outcome domains recommended for application in every clinical trial, with additional domains expanded according to specific research designs [51]. Some scholars have extended the COS definition to include relevant, reliable, and valid measurement tools [52]. The 10 retrieved articles covered measures including pain, functional disability, quality of life, psychological status, social function, and patient satisfaction. Three articles graded the importance of measures in COS, four mentioned that patient satisfaction measures should be included, and five mentioned that psychological status measures should be included. Nine articles selected different measurement tools for different domains, some of which lack Chinese versions; one article mentioned that COS should include Traditional Chinese Medicine-related clinical outcome measures but did not specify which tools; one article graded the included outcome measures but did not select appropriate measurement tools. The number of measurement tools selected varied across articles, with Chiarotto 2015 [59] selecting 3 tools and Klokkerud 2017 [58] selecting 12 tools. The current status of existing nonspecific low back pain COS is provided in Annex Table 3 .

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## Discussion

### 3 Similarities and Differences Between Acupuncture RCT Outcome Measures and Existing COS

Comparison revealed varying degrees of overlap between acupuncture RCTs and existing COS, along with notable differences.

**3.1 Similarities** Both acupuncture RCTs and existing COS cover outcome measures related to pain, functional disability, quality of life, psychological status, and patient satisfaction. However, substantial differences exist in measure selection across different COS and across different acupuncture RCTs.

**3.2 Differences** Measurement tools for outcome domains differ between acupuncture studies and international research. International COS place greater emphasis on psychological status measures, social function measures, and outcomes related to daily living abilities and coping strategies for low back pain. Domestic COS tend to focus more on clinical symptoms.

As a traditional medicine of China, Traditional Chinese Medicine has also developed COS for chronic low back pain clinical research and proposed TCM-related clinical outcome measures, though measurement tools are not yet available. The composite measure “effective rate” is widely used in acupuncture RCTs, but standards remain inconsistent.

## 4.1 Characteristics of Outcome Measure Selection in Acupuncture RCTs for CNSLBP

Although many RCTs of acupuncture for CNSLBP exist with increasingly improved methodological quality, most currently have the following problems in outcome measure selection:

**4.1.1 Unclear Primary and Secondary Outcome Measures** Most studies do not distinguish between primary and secondary outcome measures and do not calculate sample size based on any specific outcome measure, which is not conducive to reflecting the authenticity of research results [64]. Additionally, measures are not selected with reference to existing COS, possibly due to researchers' objectives, cultural differences, and the lack of formally validated Chinese versions of measurement tools.

**4.1.2 Unclear Measurement Time Points** The timing of outcome measurement varies considerably across studies, yet is closely related to sample size calculation and requires advance planning. While drug half-lives are well-established in clinical research, the duration of acupuncture effects and changes in efficacy values remain unclear. Therefore, efficacy evaluation in acupuncture may require more frequent and numerous assessment time points than drug evaluation to avoid missing critical onset points.

**4.1.3 High Heterogeneity in Number of Measures Selected** This issue mirrors that of existing COS. In early research stages where efficacy is uncertain, researchers tend to select multiple outcome measures, which increases trial difficulty, reduces outcome reliability, and does not correlate positively with research quality [67]. Therefore, future acupuncture clinical trials should carefully select an appropriate number of outcome measures.

**4.1.4 Non-standardized Application of Measures** The internationally recognized measure similar to "effective rate" is "Response rate," generally defined as improvement beyond a certain threshold on an important outcome measure. The "Effective Rate" criteria in the "Diagnostic and Therapeutic Criteria of Traditional Chinese Medicine Diseases" lack unified, universal standards and have not gained international academic recognition.

**4.1.5 Emphasis on Efficacy Measures, Neglect of Safety Measures** Key elements for reporting adverse events in RCTs should include: specific names of adverse events; frequency, duration, and severity, and relationship to treatment; and whether management measures are required [66]. Reports of adverse events in the included RCTs were brief and did not meet current reporting standards, with corresponding reporting procedures and management processes overly simplified by researchers.

## 4.2 Role of Existing COS in Acupuncture Clinical Research

COS for nonspecific low back pain and corresponding measurement tool sets have been developed domestically and internationally. Some studies have also proposed developing Intervention-related Specific Outcome Sets (In-SOS) that, in addition to COS outcomes, include characteristic outcomes representative of specific interventions [67].

Existing acupuncture RCT outcome measures may inadequately address psychological status and social function due to differences in socioeconomic, cultural, and medical backgrounds, and also lack research on economic indicators [68]. Existing COS provide valuable references for outcome measure selection in acupuncture RCTs, but must be combined with characteristics of acupuncture interventions. While drug therapy has clear targets, acupuncture typically involves a set of acupoints with potentially multi-target effects and multi-system adjustments. Therefore, outcome measures in acupuncture clinical research need not be limited to specific symptoms; multiple outcomes can be selected. Composite measures are also well-suited for acupuncture clinical research, such as the Oswestry Disability Index (ODI), which covers not only pain evaluation but also impact on daily living, sleep, travel, social activities, and sexual life.

## 4.3 Limitations of This Study

Following similar studies, this analysis only examined outcome measures in acupuncture RCTs for CNSLBP published in the past five years. While five years provides substantial representativeness, some selection bias may still exist.

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## Conclusion

Outcome measures in acupuncture RCTs for CNSLBP published in the past five years show some differences from existing COS and have several problems. Future acupuncture studies should refer to established COS and commonly used measurement tools when designing outcome measures, while expanding with appropriate recognized outcome measures based on the specific characteristics of the study.

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## Author Contributions

Yu Jinna: Study design and conceptualization

Yan Wenxi, Zhang Pingping, Fei Jingwen, Shen Jianghong, Liu Lanping, Wang Xiang, Zhu Kexin: Literature screening, data analysis, table preparation

Yang Tao: Project leader, research funding support

Lin Huize: Draft manuscript preparation, initial writing

Lin Huize, Yu Jinna: Manuscript review and quality control, overall responsibility for the article

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## Conflict of Interest

The authors declare no conflict of interest.

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## References

- [1] Expert group of Spine and Spinal Cord Professional Committee of Chinese Association of Rehabilitation Medicine. Chinese expert consensus on diagnosis and treatment of acute/chronic non-specific low back pain[J]. Chinese Journal of Spine and Spinal Cord, 2016,26(12):1134-1138. DOI:10.3969/j.issn.1004-406X.2016.12.16.
- [2] Bardin LD, King P, Maher CG. Diagnostic triage for low back pain: a practical approach for primary care[J]. Med J Aust, 2017,206(6):268-273. DOI:10.5694/mja16.00828.
- [3] Hoy D, Bain C, Williams G. et al. A systematic review of the global prevalence of low back pain[J]. Arthritis Rheum, 2012,64(6):2028-2037. DOI:10.1002/art.34347.
- [4] Hoy D, March L, Brooks Petal. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study[J]. Ann Rheum Dis, 2014,73(6):968-9746. DOI:10.1136/annrheumdis-2013-204428.
- [5] YANG X Y, ZHAO H, LIU J, et al. Application status of acupuncture in domestic and foreign guidelines for low back pain[J]. Chinese Acupuncture and Moxibustion, 2019,39(08):908-912. DOI:10.13703/j.0255-2930.2019.08.029.
- [6] DONG C, ZHAO J X. Research progress of clinical efficacy evaluation of traditional Chinese medicine[J]. Global Traditional Chinese Medicine, 2016,9(1):110-115. DOI:10.3969/j.issn.1674-1749.2016.01.035.
- [7] ZHANG D, ZHANG M Y, ZHENG W K, et al. Construction of core index set for clinical trials of traditional Chinese medicine and implementation standard of Delphi method[J]. Journal of Traditional Chinese Medicine, 2017,58(1):20-22. DOI:10.13288/j.11-2166/r.2017.01.006.
- [8] DAI L L, XU Z M, LIANG X, et al. Current status of outcome indicators in randomized controlled trials of acupuncture for acute ischemic stroke in the past three years[J]. Chinese Journal of Traditional Chinese Medicine, 2021,46(12):2949. DOI:10.19540/j.cnki.cjcm.20210316.502.
- [9] GUO X F, LAI S X, LIANG X W. Selection and application of outcome indicators in clinical efficacy evaluation of traditional Chinese medicine[J]. Jour-

nal of Guangzhou University of Traditional Chinese Medicine, 2002(04):251-255. DOI:10.3969/j.issn.1007-3213.2002.04.002.

[10] LI J, ZHANG Z P, XIONG X J, et al. A randomized controlled study of Wenxin decoction in the treatment of unstable angina pectoris[J]. Chinese Journal of Experimental Formulary Science, 2016,22(4):154-158. DOI:10.13422/j.cnki.syfjx.2016040154.

[11] WANG Y Y, WANG Y N, LIU L X, et al. Study on the effect of wrist-ankle acupuncture on lumbar muscle Strain by increasing serum  $\beta$ -endorphin level[J]. Chinese Modern Doctors, 2017,55(3):22-25.

[12] TIAN J, NIU J. Clinical effect of Yisui Tongdu acupuncture on chronic non-specific low back pain[J]. Journal of Clinical Military Medicine, 2019,47(6):618-619. DOI:10.16680/j.1671-3826.2019.06.26.

[13] CAO G Y, YANG Q Y, CHEN Y X. Clinical observation on the treatment of non-specific low back pain with fire needling combined with warming acupuncture and cupping[J]. International Medicine and Health Review, 2019,25(16):2780-2783. DOI: 10.3760/cma.j.issn.1007-1245.2019.16.055.

[14] WANG L M, DONG B Q, LIN X X, et al. A randomized clinical controlled study on the treatment of non-specific low back pain with Acupuncture at Jiejin focus points and meridian points[J]. Journal of Practical Chinese Medicine, 2020,34(3):13-15. DOI: 10.13729/j.issn.1671-7813.Z20191183.

[15] ZHENG H L. Clinical observation on the treatment of lumbar three transverse process syndrome by short needling of Ashi point[J]. Guangming Traditional Chinese Medicine, 2019,34(5):757-759. DOI: 10.3969/j.issn.1003-8914.2019.05.043.

[16] XIE L H, CAI L B. Effect observation of electroacupuncture combined with balance cupping on chronic lumbar muscle strain[J]. Inner Mongolia Traditional Chinese Medicine, 2017,36(9):107-108. DOI: 10.3969/j.issn.1006-0979.2017.09.098.

[17] BAO J Y. Key points of comprehensive treatment with acupuncture and moxibustion for 87 cases of lumbar three transverse process syndrome[J]. Diet and health, care2020,(48):127.

[18] Klassen E, Wiebelitz KR, Beer AM. Classical Massage and Acupuncture in Chronic Back Pain - Non-Inferiority Randomised Trial[J]. Z Orthop Unfall, 2019,157(3):263-269. DOI:10.1055/a-0715-2332.

[19] Kong JT, Puetz C, Tian L, et al. Effect of Electroacupuncture vs Sham Treatment on Change in Pain Severity Among Adults With Chronic Low Back Pain: A Randomized Clinical Trial[J]. JAMA Netw Open, 2020,3(10):e2022787. DOI:10.1001/jamanetworkopen.2020.22787.

[20] Kizhakkeveettil A, Rose KA, Kadar GE, et al. Integrative Acupuncture and Spinal Manipulative Therapy Versus Either Alone for Low Back Pain: A

Randomized Controlled Trial Feasibility Study[J]. *J Manipulative Physiol Ther*, 2017,40(3):201-213. DOI:10.1016/j.jmpt.2017.01.002.

[21] WANG Z Q. Clinical effect of coarse needle and short needling on lumbar three transverse process syndrome[J]. *Health care Guide*,2018,(50):204. DOI:10.3969/j.issn.1006-6845.2018.50.198.

[22] YU S L, WANG J B, YANG Q T. Effect of electroacupuncture at Jiaji point on anxiety and fatigue in patients with chronic low back pain[J]. *Modern Distance education of Traditional Chinese Medicine* ,2020,18(24):106-108. DOI:10.3969/j.issn.1672-2779.2020.24.043.

[23] ZHAO Z S, ZHU D Y, LIN J, et al. Clinical observation on 38 cases of third lumbar transverse process syndrome treated by electroacupuncture combined with stagnating acupuncture[J]. *Rheumatism and Arthritis*,2018,7(1):23-25. DOI:10.3969/j.issn.2095-4174.2018.01.005.

[24] ZHU Y. Clinical effect of lateral needling in the treatment of iliolumbar triangle syndrome[J]. *Healthy Vision*,2020,(22):40.

[25] SHI Y, DONG B Q, LIN X X,et al. Evaluation of the effect of acupuncture on non-specific low back pain based on the theory of meridian sinew[J]. *Journal of Practical Chinese Medicine Internal Medicine*, 2020,34(4):76-79. DOI: 10.13729/j.issn.1671-7813.Z20191182.

[26] LI J. Effect of new electroacupuncture therapy on low back pain in recruits[C]. *Proceedings of 2017 Academic Annual Meeting of Professional Committee of Traditional Chinese Medicine and Chinese Pharmacy of PLA*, 2017:152-161.

[27] LI J H. Clinical observation on the treatment of chronic non-specific low back pain with oblique needling at Ashi point[J]. *Journal of Shanxi University of Traditional Chinese Medicine*,2017,18(6):50-52.

[28] XU W J. Clinical efficacy of cupping therapy combined with acupuncture in the treatment of lumbodorsal myofascial pain syndrome[J]. *Modern medicine application in China*,2020,14(3):209-211. DOI:10.14164/j.cnki.cn11-5581/r.2020.03.102.

[29] YI J, WANG Z, CHEN W. Clinical Study on the treatment of Blood stasis Type Lumbar Muscle Strain by acupuncture and warming acupuncture[J]. *Chinese Health and Nutrition*,2020,30(14):56.

[30] ZHU Y Y, ZHANG Y L, WANG Y F, et al. Effect of Canglong wagging tail acupuncture on pain in patients with chronic lumbar muscle strain[J]. *Diet and health care*,2017,4(26):117. DOI:10.3969/j.issn.2095-8439.2017.26.144.

[31] LI Y J, ZHUANG W S, CAI X F, et al. Effect of acupuncture at “iliolumbar three points” on lumbar function and pain in patients with iliopsoas strain[J]. *Chinese acupuncture*,2019,39(12):1279-1282. DOI:10.13703/j.0255-2930.2019.12.006.

- [32] ZHU J W, DONG B Q, LIN X X, et al. Clinical observation on the treatment of chronic non-specific low back pain with acupuncture of sinew meridian combined with conventional acupuncture[J]. Journal of Practical Chinese Medicine Internal Medicine,2020,34(7):40-43. DOI:10.13729/j.issn.1671-7813.z20200382.
- [33] LIN Y X, LIU T M. Clinical observation of acupuncture treatment of lumbar dorsal myofasciitis [J]. Shanxi Traditional Chinese Medicine,2018,34(12):28-29. DOI:10.3969/j.issn.1000-7156.2018.12.013.
- [34] ZHANG M, NIE W T, GUO Y, et al. Effect of remote moving along meridians combined with penetrating needling at Yang meridian on mild to moderate lumbar dorsal myofasciitis[J]. Chinese acupuncture,2019,39(8):817-820. DOI:10.13703/j.0255-2930.2019.08.005.
- [35] WEN X Q, LIN R Y. Effect of acupuncture for reinforcing and reducing manipulation combined with meridian points and lidocaine block in the treatment of lumbar myofascial pain syndrome[J]. Yunnan Journal of Traditional Chinese Medicine,2021,42(5):58-60. DOI: 10.16254/j.cnki.53-1120/r.2021.05.018.
- [36] WANG Y Y, WANG Y N, LIU L X. Effect of wrist-ankle acupuncture in the treatment of lumbar muscle strain in submariners[J]. Chinese Journal of Nautical Medicine and Hyperbaric Medicine,2017,24(4):319-321. DOI:10.3760/cma.j.issn.1009-6906.2017.04.019.
- [37] LV Z. Clinical effect of acupuncture at Shusanli point combined with Yaojiaji point on chronic lumbar muscle strain [J]. Journal of Rational Use of Drugs in Clinical Practice,2018,11(14):123-124. DOI:10.15887/j.cnki.13-1389/r.2018.14.080.
- [38] GU F F, ZHU G F, LUO K T, et al. Clinical effect of warm acupuncture and moxibustion on chronic lumbar muscle strain[J]. Acupuncture and Moxibustion and Tuina Medicine (English version) ,2018,16(3):176-179. DOI:10.1007/s11726-018-1046-y.
- [39] YANG Y Q, LI S, ZHOU X Y, et al. Clinical study of Tiaoshen Zhitong acupuncture in the treatment of chronic lumbar muscle strain[J]. Inner Mongolia Traditional Chinese Medicine,2019,38(3):62-64. DOI:10.16040/j.cnki.cn15-1101.2019.03.042.
- [40] HUANG J, ZENG Y, SONG G X, et al. Effect of acupuncture therapy on lumbar myofasciitis[J]. Massage and Rehabilitation Medicine,2018,9(6):38-39. DOI:10.19787/j.issn.1008-1879.2018.06.017.
- [41] SHI F Y, DONG B Q, LIN X X, et al. Clinical observation of combined waist and abdomen acupuncture for non-specific low back pain based on the theory of meridian sinew[J]. Journal of Practical Chinese Medicine Internal Medicine,2021,35(2):93-96. DOI:10.13729/j.issn.1671-7813.Z20200427.
- [42] LI Z M, BAO W L. Clinical efficacy of Xiaoliuhe acupuncture in the treatment of non-specific low back pain[J]. Journal of Kunming Medical University,2020,41(1):137-140. DOI:10.3969/j.issn.1003-4706.2020.01.025.

- [43] LIN J, CHENG Y, DAI R S. Clinical observation of Qi-Huang acupuncture therapy for non-specific low back pain[J]. *Guangming Traditional Chinese Medicine*,2020,35(23):3756-3758. DOI:10.3969/j.issn.1003-8914.2020.23.035.
- [44] LV Z L. Clinical study of warming acupuncture in the treatment of cold-damp type lumbar muscle strain[J]. *New Traditional Chinese Medicine*,2019,51(8):247-249.
- [45] CHENG L L, WANG X L, LIU Y L. Clinical observation on the treatment of the third lumbar transverse process syndrome with acupuncture method[J]. *Huaxia Medicine*,2020,33(2):118-120. DOI:10.19296/j.cnki.1008-2409.2020-02-032.
- [46] LAI P H, DENG H H, WU J M, et al. Clinical study of electric warming acupuncture in the treatment of cold-damp type nonspecific low back pain[J]. *Clinical Journal of Acupuncture and Moxibustion*,2019,35(1):30-33. DOI:10.3969/j.issn.1005-0779.2019.01.009.
- [47] YANG Z Q, HU Z P. Clinical observation on the treatment of the third lumbar transverse process syndrome by electroacupuncture combined with motion pot method[J]. *Journal of Practical Chinese Medicine*,2020,36(3):378-379.
- [48] LI X Y, LI J. Clinical effect of acupuncture-cupping “Jinlao point” in the treatment of the third lumbar transverse process syndrome[J]. *Health care guidelines*,2021,(29):110.
- [49] QIAN H, YIN T, HE L X, et al. Clinical study on the treatment of chronic non-specific low back pain with acupuncture and moxibustion Tiaoshen Jianpi method[J]. *New Traditional Chinese Medicine*,2022,54(03):177-182. DOI:10.13457/j.cnki.jncm.2022.03.039.
- [50] DU JUN. Acupuncture at Qi Point of Dong’ s Family combined with electroacupuncture at Ashi Point for the treatment of 50 cases of the Third Lumbar transverse process syndrome[J]. *Chinese national and folk medicine*, 2017,26(21):107-108.
- [51] LIU J C, DONG B Q, LIN X X. Clinical observation of warming acupuncture and moxibustion combined with syndrome differentiation in the treatment of the third lumbar transverse process syndrome[J]. *Journal of Liaoning University of Traditional Chinese Medicine*,2017,19(3):143-146. DOI:10.13194/j.issn.1673-842x.2017.03.040.
- [52] Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider[J]. *Trials*. 2012,6(13):132. DOI: 10.1186/1745-6215-13-132.
- [53] Schmitt, J., Apfelbacher, C., Spuls, P.I., et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: A methodological framework to develop core sets of outcome measurements in dermatology[J]. *Investig. Dermatol.*2015,135(1):24-30. DOI:10.1038/jid.2014.320.

- [54] Coe-O' Brien R, Joseph L, Kuisma R, et al. Outcome measures used in the smartphone applications for the management of low back pain: a systematic scoping review[J]. *Health Inf Sci Syst.* 2020,8(1):5. DOI: 10.1007/s13755-019-0097-x.
- [55] Turk DC, Dworkin RH, Allen RR, et al. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations[J]. *Pain.* 2003,106(3):337-345. DOI: 10.1016/j.pain.2003.08.001.
- [56] Reneman MF, Beemster TT, Edelaar MJ, et al. Towards an ICF- and IMMPACT-based pain vocational rehabilitation core set in the Netherlands[J]. *J Occup Rehabil.* 2013,23(4):576-84. DOI: 10.1007/s10926-013-9423-3.
- [57] Deyo RA, Battie M, Beurskens AJ, et al. Outcome measures for low back pain research. A proposal for standardized use[J]. *Spine (Phila Pa 1976).* 1998,15;23(18):2003-13. DOI: 10.1097/00007632-199809150-00018.
- [58] Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders: summary and general recommendations[J]. *Spine (Phila Pa 1976).* 2000,15;25(24):3100-3. DOI: 10.1097/00007632-200012150-00003.
- [59] Klokkerud, M., Dagfinrud, H., Uhlig, T., et al. Developing and testing a consensus-based core set of outcome measures for rehabilitation in musculoskeletal diseases[J]. *Scandinavian journal of rheumatology.* 2018, 47(3): 225-234. DOI: 10.1080/03009742.2017.1347959.
- [60] Chiarotto, Deyo, R.A., Terwee, C.B. et al. Core outcome domains for clinical trials in non-specific low back pain[J]. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society.* 2015, 24(6): 1127-42. DOI:10.1007/s00586-015-3892-3.
- [61] Clement, R. C., Welandar, A., Stowell, C., et al. A proposed set of metrics for standardized outcome reporting in the management of low back pain[J]. *Acta orthopaedica,*2015 ,86(5), 523-533. DOI:10.3109/17453674.2015.1036696.
- [62] Chapman, J. R., Norvell, D. C., Hermsmeyer, et al. Evaluating common outcomes for measuring treatment success for chronic low back pain[J]. *Spine,* 2011, 36(21):S54-68. DOI:10.1097/BRS.0b013e31822ef74d.
- [63] HOU W M, LIN T Q. Construction of efficacy evaluation index system for chronic non-specific low back pain based on Delphi method[J]. *Health required,*2019,(33):293-294.
- [64] WANG Y. Construction of the core outcome index set of traditional Chinese medicine clinical research in chronic low back pain[D]. *Beijing University of Chinese Medicine,*2021. DOI:10.26973/d.cnki.gbjzu.2021.000702.
- [65] DONG F, LI C, PENG X X, et al. The significance, calculation method and precautions of sample size calculation in clinical research[J]. *Chinese Journal of Stroke,*2009,4(10):854-859. DOI:10.3969/j.issn.1673-5765.2009.10.020.

- [66] WU Y N, WAN Y, HU C Y, et al. A Comparative Study of Outcomes and Measurements Used in Randomized Controlled Trials for Low Back Pain Treated by Western Medicine and Traditional Chinese Medicine[J/OL]. General practice in China:1-10[2022-08-31].<http://kns.cnki.net/kcms/detail/13.1222.R.20220826.0907.004.html>.
- [67] John PAI, Stephen JWE, Peter CG, et al. Better reporting of harms in randomized trials: the CONSORT statement Extension[J]. Chinese Journal of Evidence-Based Medicine, 2006,6(9):682-689. DOI:10.3969/j.issn.1672-2531.2006.09.013.
- [68] XIA J, LIU H B, LIU X, et al. Interpretation of GRADE guidelines 20: Assessing the certainty of evidence in the importance of outcomes or values and preferences-inconsistency, imprecision, and other domains[J]. Chinese Journal of Evidence-Based Pediatrics, 2021,16(6):449-451. DOI:10.3969/j.issn.1673-5501.2021.06.010.
- [69] SUN Y N, LIU Y L, GUO JM, et al. Establishment of Traditional Chinese Medicine Specific Outcome Set[J]. Journal of Traditional Chinese Medicine, 2021,62(13):1134-1137. DOI:10.13288/j.11-2166/r.2021.13.008.

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## Annex 1 Basic Characteristics of the Literature

[Table content with study characteristics]

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## Annex 2 Different Definitions of Response Rate in Each Study

[Table content with various response rate definitions]

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## Annex 3 Current Status of the Existing COS of Nonspecific Low Back Pain

[Table content summarizing existing core outcome sets]

*Note: Figure translations are in progress. See original paper for figures.*

*Source: ChinaXiv – Machine translation. Verify with original.*