

BMJ Open

Acupuncture for sciatica: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-007498
Article Type:	Protocol
Date Submitted by the Author:	19-Dec-2014
Complete List of Authors:	Qin, ZongShi; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Xiaoxu; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Yao, Qin; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Zhai, Yanbing; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Zhishun; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	Evidence based practice, Neurology, Medical publishing and peer review
Keywords:	COMPLEMENTARY MEDICINE, Neurological pain < NEUROLOGY, Neuropathology < NEUROLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PAIN MANAGEMENT

SCHOLARONE™
Manuscripts

Only

Acupuncture for sciatica: a systematic review protocol

Zongshi Qin,^{1,2} Xiaoxu Liu,^{1,2} Qin Yao,^{1,2} Yanbin Zhai,^{1,2} Zhishun Liu^{1*}

¹Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese

Medical Sciences, Beijing 100053, China

² Graduates School, Beijing University of Chinese Medicine, Beijing 100029, China

*Correspondence to: Professor Zhishun Liu, Tel.: 86-10-88001124, E-mail: liuzhi

shun@aliyun.com

Running title: Acupuncture for sciatica: a systematic review protocol

Key words: acupuncture, sciatica, systematic review, protocol

Word count: 2,059

ABSTRACT

1
2
3
4
5
6 **Introduction:** This systematic review aims to assess the effectiveness and safety of
7
8
9 acupuncture for treating sciatica.

10
11 **Methods:** The following nine databases will be searched from their inception to 30 October
12
13 2014: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials
14
15 (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current
16
17 Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database,
18
19 China National Knowledge Infrastructure (CNKI), and Citation Information by National
20
21 Institute of Informatics (CiNii). Randomized controlled trials of acupuncture for sciatica in
22
23 English, Chinese, or Japanese without restriction of publication status will be included. Two
24
25 researchers will independently undertake study selection, extraction of data, and assessment
26
27 of study quality. Meta-analysis will be conducted after screening of studies. Data will be
28
29 analyzed using risk ratio for dichotomous data, and standardized mean difference or weighted
30
31 mean difference for continuous data.
32
33
34
35
36
37
38

39 **Dissemination:** This systematic review will be disseminated electronically and in print in a
40
41 peer-reviewed publication.
42
43

44 **Trial registration number:** PROSEPRO CRD42014015001
45
46
47
48

49 **Strengths and limitations of this study**

- 50 • The efficacy of conservative therapy for sciatica is uncertain, and acupuncture may
51
52 provide an effective alternative treatment method. To the best of the authors' knowledge,
53
54
55
56
57
58
59
60

1
2
3
4 there is currently no systematic review published in English related to acupuncture for
5
6 sciatica. The results of this systematic review will help clinicians make decisions on
7
8 treating sciatica, and help patients seeking further treatment options.
9

- 10
11 • The inclusion of Japanese medical databases is a potential advantage of this systematic
12
13 review, as Japanese medicine has been influenced by traditional Chinese medicine over a
14
15 long period of time.
16
17
- 18
19 • One limitation of this systematic review is that because of the language barrier, trials in
20
21 only three languages can be included. Hence, relevant studies published in other
22
23 languages might be missed.
24
25
- 26
27 • Another limitation is that the different forms of acupuncture therapy and quality of
28
29 methodologies in the included studies may cause significant heterogeneity.
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

INTRODUCTION

Sciatica is a common neuropathy characterized by pain radiating into the leg; it is usually caused by nerve root compression and irritation or inflammation of the sciatic nerve, and is often accompanied by lower back pain and neurological deficits in the lower limb.^[1] The pain is often associated with tingling, numbness, and weakness of the leg; it may be sudden in onset and then persist for days or weeks.^[2] Frymoyer reported that sciatica is very common, with a lifetime incidence varying from 13% to 40% and a corresponding annual incidence of sciatica episodes of 1–5%.^[3,4]

Sciatica commonly affects people between the ages of 30 and 50 years, with the pain of sciatica significantly damaging health.^[5] Thus, sciatica has become a major cause of work absenteeism and a financial burden to society.^[6] Previous research has reported that 60% of patients with sciatica will have a mild disability and there is an assignable number of patients that live with sciatica for more than 1 year, which results in an obvious decrease in quality of life.^[7]

The current management of sciatica can be classified into pharmacological and non-pharmacological treatment, neither of which provides a completely satisfactory treatment option.^[8] The use of pharmacological products such as anesthetics or corticosteroids has associated adverse effects including sedation, dizziness, ataxia, and nausea, and their effectiveness decreases with long-term use.^[9] An existing published systematic review and meta-analysis found that epidural injection has no significant effect on sciatica pain, although

1
2
3 related adverse effects to epidural injections have been confirmed.^[10-12] To date, there is no
4
5 strong evidence-based medicine proving that non-pharmacological conservative treatment of
6
7
8 Western medicine is effective^[13,14], and surgical procedures are invasive, expensive, and may
9
10 cause neurological complications.^[15]

11
12
13
14 Currently, sciatica is one of the primary reasons for hospital consultations. Acupuncture
15
16 has become a widely used method for treating sciatica in many countries, including China, the
17
18 USA, and Japan. Acupuncture is reported to be effective in treating many types of
19
20 musculoskeletal pain including lower back pain,^[16] fibromyalgia,^[17] osteoarthritis,^[18] and
21
22 sciatica.^[19-23] However, the ability of acupuncture to successfully manage sciatica, either as a
23
24 monotherapy or as an adjunct to Western medical care, remains unclear.
25
26
27

28
29 This systematic review aims to assess the efficacy and safety of acupuncture for treating
30
31 sciatica, with the resulting evaluation aiming to help clinicians make decisions on treating
32
33 sciatica, and to help patients seeking further treatment options.
34
35
36

37 38 39 **METHODS AND ANALYSIS**

40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
Criteria for inclusion of studies in this review:

Types of studies

Only randomized controlled trials (RCTs) will be included; quasi-RCTs and randomized
crossover studies will be excluded. Blinding will not be considered because of the
characteristics of acupuncture treatment.

Types of participants

Patients with sciatica will be included, including those diagnosed with sciatica synonyms such as radiculopathy, nerve root compromise, nerve root compression, nerve root pain, and pain radiating below the knee. There will be no restriction on sex, age, or the intensity or duration of symptoms.

Patients with acute infection, caudal equina syndrome, primary spinal stenosis, and lower back pain without sciatica will be excluded.

Types of interventions

- Any type of invasive acupuncture will be included, such as acupuncture, electro-acupuncture, elongated needle acupuncture, three-edged needle acupuncture, fire needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and pyonex. Control interventions may include general care, sham acupuncture/placebo, and waiting list care.
- Acupuncture versus other Western medicine treatment will be included.
- Acupuncture plus another Western medicine treatment versus the same Western medicine treatment alone will be included.
- RCTs comparing two different types of acupuncture will be excluded.
- Acupuncture treatment without needle insertion (e.g., acupressure, laser acupuncture, and electrical stimulation) will be excluded.
- Acupuncture combined with Chinese medicine, acupoint injection, and/or needle knife

1
2
3 will be excluded.
4
5
6
7
8

9 **Types of outcome assessments**

10
11 Primary outcomes:

- 12
13
14 • Pain intensity. Any validated measurement scales will be included (e.g., visual analog
15
16 scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire
17
18 (SF-MPQ)).
- 19
20
21 • Global assessment (the proportion of patients improved or cured).
22
23

24
25 Secondary outcomes:

- 26
27 • Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form
28
29 health survey (SF-36)
- 30
31 • Physical examinations.
- 32
33 • Patient satisfaction.
- 34
35 • Adverse effects.
36
37
38
39
40
41

42 **Search methods for identification of studies**

43
44 The following nine databases will be searched from their inception to 30 October 2014:

45
46 MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL),
47
48 Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC),
49
50 Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National
51
52 Knowledge Infrastructure (CNKI), and Citation Information by National Institute of
53
54 Informatics (CiNii). The search strategy is based on the guidance of the Cochrane handbook.
55
56
57
58
59
60

1
2
3
4 The key words include “sciatica”, “sciatic neuralgia”, “discogenic sciatica”, “disc
5
6 herniation-induced sciatica”, “bilateral sciatica”, “acupuncture”, “electro-acupuncture”,
7
8
9 “elongated needle”, “three-edged needle”, “fire needling”, “auricular acupuncture”,
10
11
12 “abdominal acupuncture”, and “pyonex”.

13
14
15
16 The strategy for searching the PUBMED database is shown in Appendix 1. This search
17
18
19 strategy will also be applied to the other electronic databases.
20
21
22
23

24 **Data collection and analysis**

25 *Selection of studies*

26
27
28 Two authors (XL and YZ) will screen the title and abstracts of all the articles to confirm that
29
30
31 they contain eligible trials, with the full text to be reviewed if necessary. Any disagreement
32
33
34 during the selection of studies will be discussed and decided by a third author (ZL). Details of
35
36
37 the selection process are shown in the PRISMA flow chart (Figure 1).
38
39
40
41

42 *Data extraction and management*

43
44 A data extraction form will be used to collect data. A small scope trial will be done before the
45
46
47 systematic review is conducted to confirm that there is no obvious divergence between those
48
49
50 collecting data. Two authors (XL and YZ) will independently extract the data and take the
51
52
53 following aspects into consideration: general information (name and year of publication, date
54
55
56 of extraction, title of study, and author’s publication details), study characteristics, eligibility
57
58
59 criteria, interventions, outcome measurements, duration, adverse events, results, and the type
60

1
2
3
4 of needle used. These data will then be entered into RevMan 5.3.3 software for analysis. Any
5
6 disagreement will be discussed and finally decided upon by a third author (ZL).
7
8
9

10 11 *Assessment of risk of bias in included studies*

12
13
14 The risk of bias assessment will be based on the Cochrane Collaboration Risk of Bias Tool.^[24]
15
16 Two authors (QY and YZ) will independently evaluate methodological quality using the
17
18 following seven domains: random sequence generation, allocation concealment, blinding of
19
20 participants and personnel, blinding of outcome assessment, incomplete outcome data,
21
22 selective reporting, and other bias. Other sources of bias may be caused by the different types
23
24 of needles used, the duration of sciatica, the length of therapy, and the age of patients. Taking
25
26 these domains into account, each trial will be categorized into low risk, high risk, and unclear
27
28 risk. Any disagreements will be discussed and resolved by a third author (ZL).
29
30
31
32
33
34
35
36

37 *Measurement of treatment effect*

38
39 Analysis will be based on available data of included studies. For dichotomous data, the risk
40
41 ratio (RR) will be calculated with 95% confidence intervals (CIs). For continuous variables,
42
43 means and standard deviations will be used to calculate a mean difference with a 95% CI.
44
45
46
47
48

49 *Dealing with missing data*

50
51 The listed corresponding author will be contacted to try and obtain any missing information
52
53 from their trial. If it is impossible to obtain the data, the study will be excluded from the data
54
55 synthesis.
56
57
58
59
60

Assessment of heterogeneity

Before combining the statistics, tests for heterogeneity will be used to judge the homogeneity of the studies. If the resulting p value exceeds 0.1, indicating significant heterogeneity among trials, the reasons leading to heterogeneity will be analyzed and subgroup analysis will be conducted.

Assessment of reporting biases

Funnel plot will be used to assess the reporting biases if 10 or more trials are included in a meta-analysis.

Data synthesis

If meta-analysis can be conducted, RevMan V.5.3.3 software will be used to combine the RR with 95% CIs for dichotomous outcomes and the weighted mean difference or standardized mean difference with 95% CIs for continuous data. If the result of the test for heterogeneity results in $p > 0.1$, the fixed-effect model will be used to combine the data; if $p < 0.1$ the random effect model will be used.

Subgroup analysis

The following subgroup analyses will be conducted to assess the heterogeneity of the studies:

Clinical considerations

- Acupuncture versus sham acupuncture

- Types of sciatica (non-discogenic sciatica versus discogenic sciatica)

Methodological considerations

- Trials with unclear or high risk of bias

Sensitivity analysis

If the test for heterogeneity p value is less than 0.1 after the data extraction has been checked and subgroup analyses conducted, the low-quality studies will be excluded and the meta-analysis will be conducted again.

Ethics and dissemination

This systematic review will not use data from individual patients to protect privacy, and the results of this systematic review will be disseminated only in a peer-reviewed publication.

DISCUSSION

Sciatica causes significant suffering for the individual, yet most of the currently available treatment options are not adequate to control pain. Pharmacological methods have associated adverse effects, while surgery is expensive and is not appropriate for every patient.

Acupuncture has been used for 3,000 years in China and is generally regarded as a safe and effective measure to alleviate pain. However, when the effectiveness of acupuncture for a condition remains unclear, it is difficult for clinicians to make appropriate recommendations.

The mechanism of acupuncture analgesia is gradually becoming known. Han found that

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

acupuncture can promote release of 5-hydroxytryptamine and endogenous opioid peptides, and change neurotransmitters to prevent the transmission of pain.^[25,26]

This is a protocol for a systematic review that aims to assess the safety and effectiveness of acupuncture for sciatica. As there has been no prior systematic review related to acupuncture for sciatica published in English, the authors' hope this systematic review will help clinicians make decisions in practice and promote the progress of acupuncture research.

This review has some potential limitations. Different forms of acupuncture therapies and quality of methodology in included trials may cause significant heterogeneity. There also may be some relevant studies missed, as only studies published in English, Chinese, and Japanese will be included.

Contributors

ZL and ZQ contributed to the conception of the study. The manuscript protocol was drafted by ZQ and revised by QY. The search strategy was developed by all the authors and will be performed by YZ and XL. YZ and XL will also independently screen the potential studies, extract data from the included studies, assess the risk of bias, and complete the data synthesis. ZL will arbitrate in cases of disagreement and ensure the absence of errors. All authors approved the publication of the protocol.

Funding statement

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests: None.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2014-007498 on 28 April 2015. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

REFERENCES

1. Stafford, M.A., Peng, P., Hill, D.A., et al., Sciatica: a review of history, epidemiology, pathogenesis, and the role of epidural steroid injection in management. *Br J Anaesth*. 2007;99:461-473.
2. Mathieson, S., Maher, C.G., McLachlan, A.J., et al., *PRECISE - pregabalin in addition to usual care for sciatica: study protocol for a randomised controlled trial*. *Trials*, 2013;14: 213.
3. Frymoyer, J.W., *Lumbar disk disease: epidemiology*. *Instr Course Lect*, 1992;41: 217-23.
4. Frymoyer, J.W., *Back pain and sciatica*. *N Engl J Med*, 1988;318: 291-300.
5. Konstantinou, K. and K.M. Dunn., *Sciatica: review of epidemiological studies and prevalence estimates*. *Spine* 2008;33: 2464-72.
6. Younes, M., Bejia, I., Aguir, Z., et al., *Prevalence and risk factors of disk-related sciatica in an urban population in Tunisia*. *Joint Bone Spine*, 2006;73:538-42.
7. Weber, H., I. Holme, and E. Amlie., *The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam*. *Spine*, 1993;18:1433-8.
8. Lewis, R.A., Willams, N.H., Sutton, A.J., et al., *Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses*. *Spine J*. Epub October 4, 2013.

- 1
2
3
4 9. Valat, J.P., Giraudeau,B.,Rozenberg,S.,et al., *Epidural corticosteroid injections for sciatica: a*
5
6 *randomised, double blind, controlled clinical trial.* Ann Rheum Dis 2003;**62**: 639-43.
7
8
9 10. Carette, S., Leclaire,R.,Marcoux,S.,et al., *Epidural corticosteroid injections for sciatica due to*
10
11 *herniated nucleus pulposus.* N Engl J Med 1997;**336** :1634-40.
12
13 11. Finckh,A.,Zufferey,P.,Schurch,M.A.,et al., *Short-term efficacy of intravenous pulse*
14 *glucocorticoids in acute discogenic sciatica. A randomized controlled trial.* Spine 2006;**31**:
15 377-81.
16
17
18 12. Korhonen,T., Karppinen,J.,Paimela,L.,et al., *The treatment of disc herniation-induced sciatica*
19 *with infliximab: results of a randomized, controlled, 3-month follow-up study.* Spine (Phila Pa
20 1976) 2005;**30**: 2724-8.
21
22
23 13. Atlas, S.J., Keller,R.B.,WU,Y.A.,et al., *Long-term outcomes of surgical and nonsurgical*
24 *management of lumbar spinal stenosis: 8 to 10 year results from the maine lumbar spine study.*
25 Spine (Phila Pa 1976) 2005;**30**: 936-43.
26
27
28 14. Legrand, E., Bouvard,B.,Audran,M.,et al., *Sciatica from disk herniation: Medical treatment or*
29 *surgery?* Joint Bone Spine 2007; **74**: 530-535.
30
31
32 15. Van Tulder MW., Koes B., Seitsalo S., et al., *Outcome of invasive treatment modalities on*
33 *back pain and sciatica: an evidence-based review.* Eur Spine J. 2006;15(Suppl 1):S82–S92.
34
35
36 16. Lee JH., Choi TY., Lee MS.,et al., *Acupuncture for acute low back pain: a systematic review.*
37 *Clin J Pain* 2013, 29:172–185. □
38
39
40
41
42 17. Iannuccelli,C., Mannocci,F., Guzzo,M.P.,et al., *Complementary treatment in fibromyalgia:*
43 *combination of somatic and abdominal acupuncture.* Clin Exp Rheumatol 2012, 30(6 Suppl
44 74):112–116
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
18. Witt,C., Brinkhaus,B., Jena,S., et al.,*Acupuncture in patients with osteoarthritis of the knee: a randomised trial*. Lancet 2005, 366:136–143. □
 19. Duplan,B., Cabanel,G.,Piton,J.L.,et al., *Acupuncture and sciatica in the acute phase. Double-blind study of 30 cases*. Sem Hop 1983; **59**: 3109-14.
 20. Zhang, P., *Essentials for the acupuncture treatment of radicular sciatica*. J Tradit Chin Med 2003;**23**: 237.
 21. Li, J., J.C. Dong, and J.J. Yue., *Effects of acupuncture on default mode network images of chronic sciatica patients in the resting network state*. Zhongguo Zhong Xi Yi Jie He Za Zhi 2012;**32**: 1624-7.
 22. Chen, M.R., Wang,P.,Cheng,G.,et al., *The warming acupuncture for treatment of sciatica in 30 cases*. J Tradit Chin Med 2009; **29**: 50-3.
 23. Wang BX, La JL. *Therapeutic effects of electro-acupuncture and diclofenic on herniation of lumbar intervertebral disc*. Zhongguo Linchuang Kangfu 2004;8:3413-5.
 24. Higgins,J.P., Altman,D.G., Gotzsche,P.C.,et al.,Cochrane Bias Methods Group; Cochrane Statistical Methods Group: The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials. BMJ 2011, 343:d5928.
 25. Han, J.S. and L. Terenius., *Neurochemical basis of acupuncture analgesia*. Annu Rev Pharmacol Toxicol 1982;**22**: 193-220.
 26. Han, J.S., *Acupuncture analgesia: its neuronal pathways and relevant neurotransmitters*. Sheng Li Ke Xue Jin Zhan 1984; **15**: 294-300.

Appendix 1

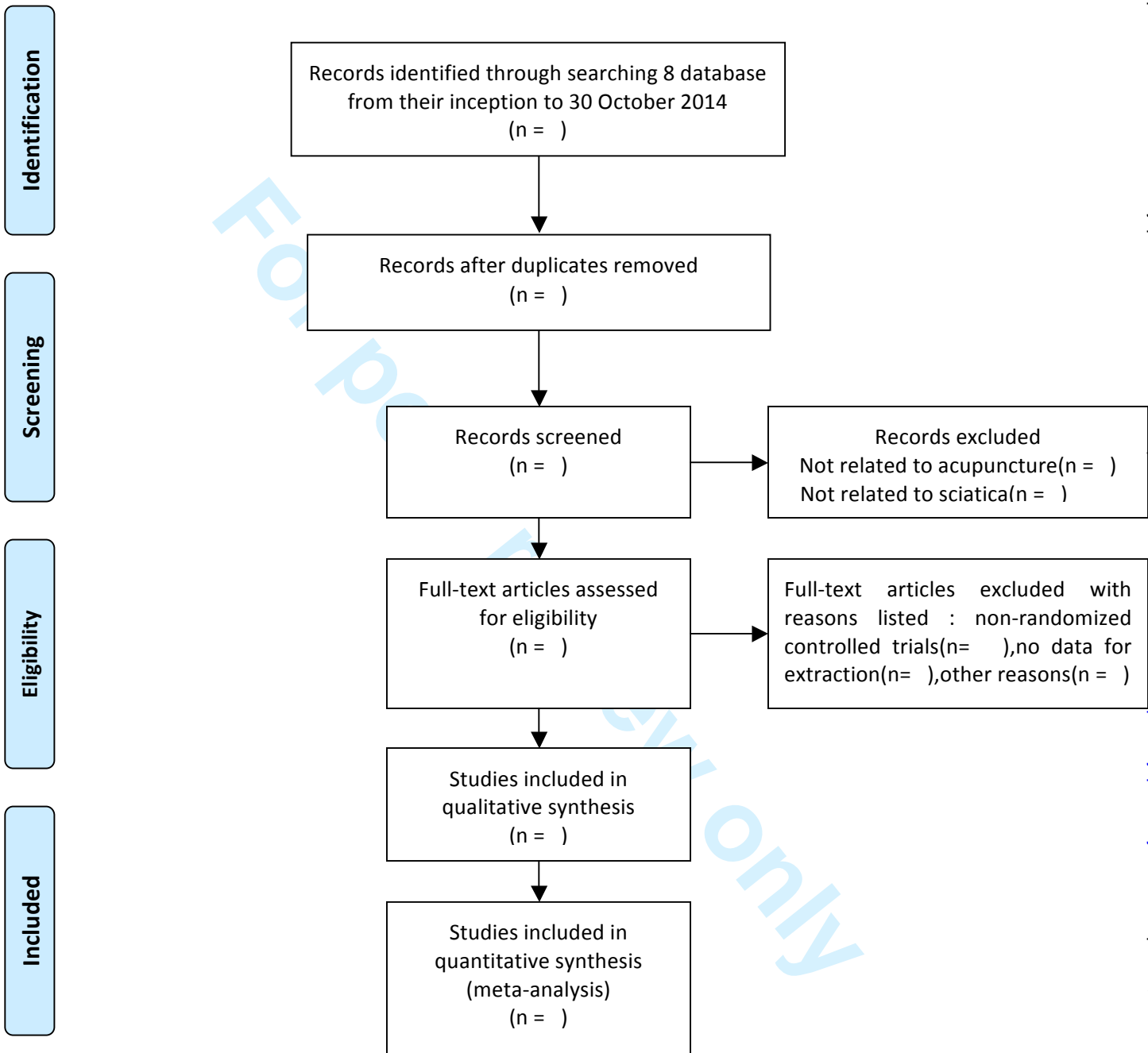
Search strategy used in PubMed database

1. randomized controlled trial.pt
2. controlled clinical trial.pt
3. randomized.ti,ab
4. randomly.ti,ab
5. groups.ti,ab
6. trial.ti,ab
7. or 1-6
8. acupuncture.ti,ab
9. electro-acupuncture.ti,ab
10. elongated needle.ti,ab
11. three edged needle.ti,ab
12. (fire needle or warming needle).ti,ab
13. auricular acupuncture.ti,ab
14. abdominal acupuncture.ti,ab
15. warm acupuncture.ti,ab
16. pyonex.ti,ab
17. or 8-16
18. sciatica.ti,ab

19. sciatic neuralgia.ti,ab
20. discogenic sciatica.ti,ab
21. bilateral sciatica.ti,ab
22. disc herniation-induced sciatica.ti,ab
23. or 18-22
24. 7 and 17 and 23

For peer review only

Figure 1 Flow diagram of the study selection process



BMJ Open

Acupuncture for sciatica: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-007498.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Feb-2015
Complete List of Authors:	Qin, ZongShi; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Xiaoxu; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Yao, Qin; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Zhai, Yanbing; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Zhishun; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	Evidence based practice, Neurology, Medical publishing and peer review
Keywords:	COMPLEMENTARY MEDICINE, Neurological pain < NEUROLOGY, Neuropathology < NEUROLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PAIN MANAGEMENT

SCHOLARONE™
Manuscripts

Only

Acupuncture for sciatica: a systematic review protocol

Zongshi Qin,^{1,2} Xiaoxu Liu,^{1,2} Qin Yao,^{1,2} Yanbin Zhai,^{1,2} Zhishun Liu^{1*}

¹Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China

² Beijing University of Chinese Medicine, Beijing 100029, China

*Correspondence to: Professor Zhishun Liu, Tel.: 86-10-88001124, E-mail: liuzhishun@aliyun.com

Running title: Acupuncture for sciatica: a systematic review protocol

Key words: acupuncture, sciatica, systematic review, protocol

Word count: 2,342

ABSTRACT

Introduction: This systematic review aims to assess the effectiveness and safety of acupuncture for treating sciatica.

Methods: The following nine databases will be searched from their inception to 30 October 2014: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics (CiNii). Randomized controlled trials of acupuncture for sciatica in English, Chinese, or Japanese without restriction of publication status will be included. Two researchers will independently undertake study selection, extraction of data, and assessment of study quality. Meta-analysis will be conducted after screening of studies. Data will be analyzed using risk ratio for dichotomous data, and standardized mean difference or weighted mean difference for continuous data.

1
2
3 **Dissemination:** This systematic review will be disseminated electronically and in print in a
4 peer-reviewed publication.
5

6 **Trial registration number:** PROSPERO CRD42014015001
7
8
9

10 11 **Strengths and limitations of this study**

- 12 • The efficacy of conservative therapy for sciatica is uncertain, and acupuncture may provide
13 an effective alternative treatment method. To the best of the authors' knowledge, there is
14 currently no systematic review published in English related to acupuncture for sciatica. The
15 results of this systematic review will help clinicians make decisions on treating sciatica, and
16 help patients seeking further treatment options.
17
- 18 • One limitation of this systematic review is that because of the language barrier, trials in only
19 three languages can be included. Hence, relevant studies published in other languages might
20 be missed.
21
- 22 • Another limitation is that the different forms of acupuncture therapy and quality of
23 methodologies in the included studies may cause significant heterogeneity.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

INTRODUCTION

Sciatica is a common neuralgia characterized by pain radiating into the leg; it is usually caused by nerve root compression and irritation or inflammation of the sciatic nerve, and is often accompanied by lower back pain and neurological deficits in the lower limb.^[1] The pain is often associated with tingling, numbness, and weakness of the leg; it may be sudden in onset and then persist for days or weeks.^[2] Frymoyer reported that sciatica is very common, with a lifetime incidence varying from 13% to 40% and a corresponding annual incidence of sciatica episodes of 1–5%.^[3,4]

Sciatica commonly affects people between the ages of 30 and 50 years, with the pain of sciatica significantly damaging health.^[5] Thus, according to the reporting of Younes.M, in Tunisia sciatica has become a major cause of work absenteeism and a financial burden to society.^[6] Previous research has reported that 60% of patients with sciatica will have a mild disability and based on questionnaires at months 3 and 12 there is 30% of patients that live with sciatica for more than 1 year, which results in an obvious decrease in quality of life.^[7] The current management of sciatica can be classified into pharmacological and non-pharmacological treatment. One reporting supports the effectiveness of nonopioid medication, epidural injections, and disc surgery. It also suggests that spinal manipulation, acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be considered.^[8] The use of pharmacological products such as anesthetics or corticosteroids has associated adverse effects including sedation, dizziness, ataxia, and nausea, and their effectiveness decreases with long-term use.^[9] Although according to the prior systematic review epidural injections has better effect for pain reduction than nonopioids,^[8] related adverse effects to epidural injections have been reported.^[10-12] To date, there is no strong evidence-based medicine proving that non-pharmacological conservative treatment of Western medicine is effective^[13,14], and surgical procedures are invasive, expensive, and may cause neurological complications.^[15]

Currently, sciatica is one of the primary reasons for hospital consultations. Acupuncture has become a widely used method for treating sciatica in many countries, including China, the USA, and Japan. Acupuncture is reported to be effective in treating many types of musculoskeletal pain including lower back pain,^[16] fibromyalgia,^[17] osteoarthritis,^[18] and sciatica.^[19-23] However,

1
2
3 the ability of acupuncture to successfully manage sciatica, either as a monotherapy or as an
4 adjunct to Western medical care, remains unclear.
5

6 This systematic review aims to assess the efficacy and safety of acupuncture for treating
7 sciatica. To this end, we will pose the following question: What is the comparative efficacy and
8 safety of acupuncture compared to sham acupuncture, usual care, or no treatment to reduce pain
9 intensity in patients diagnosed with sciatica? Is there a definitive advantage of acupuncture
10 compared with western medication? With the resulting evaluation aiming to help clinicians
11 make decisions on treating sciatica, and to help patients seeking further treatment options.
12
13
14
15
16

17 18 19 **METHODS AND ANALYSIS**

20 Criteria for inclusion of studies in this review:

21 22 **Types of studies**

23 Only randomized controlled trials (RCTs) will be included; quasi-RCTs and randomized
24 crossover studies will be excluded. Blinding will not be considered because of the characteristics
25 of acupuncture treatment.
26
27
28

29 30 31 **Types of participants**

32 Patients with sciatica will be included, including those diagnosed with sciatica synonyms such
33 as radiculopathy, nerve root compromise, nerve root compression, nerve root pain, and pain
34 radiating below the knee. There will be no restriction on sex, age, or the intensity or duration of
35 symptoms.
36
37

38 Patients with acute infection, caudal equina syndrome, primary spinal stenosis, and lower back
39 pain without sciatica will be excluded.
40
41
42

43 44 45 **Types of interventions**

- 46 • Any type of invasive acupuncture will be included, such as acupuncture,
47 electro-acupuncture, elongated needle acupuncture, three-edged needle acupuncture, fire
48 needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and pyonex.
49 Control interventions may include general care, sham acupuncture/placebo, and waiting list
50 care.
51
- 52 • Acupuncture versus other Western medicine treatment will be included.
- 53 • Acupuncture plus another Western medicine treatment versus the same Western medicine
54 treatment alone will be included.
55
56
57
58
59
60

- RCTs comparing two different types of acupuncture will be excluded.
- Acupuncture treatment without needle insertion (e.g., acupressure, laser acupuncture, and electrical stimulation) will be excluded.
- Acupuncture combined with Chinese medicine, acupoint injection, and/or needle knife will be excluded.

Types of outcome assessments

Primary outcomes:

- Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)).
- Global assessment (the proportion of patients improved or cured).

Secondary outcomes:

- Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form health survey (SF-36)
- Physical examinations.
- Patient satisfaction.
- Adverse effects.

Search methods for identification of studies

A search strategy will be used and conducted according to the Cochrane handbook guidelines.

^[24] The following nine databases will be searched from their inception to 30 October 2014:

MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics (CiNii). The search strategy is based on the guidance of the Cochrane handbook. The key words include “sciatica”, “sciatic neuralgia”, “discogenic sciatica”, “disc herniation-induced sciatica”, “bilateral sciatica”, “acupuncture”, “electro-acupuncture”, “elongated needle”, “three-edged needle”, “fire needling”, “auricular acupuncture”, “abdominal acupuncture”, and “pyonex”.

The strategy for searching the PUBMED database is shown in Appendix 1. This search strategy will also be applied to the other electronic databases.

Data collection and analysis

Selection of studies

Two authors (XL and YZ) will screen the title and abstracts of all the articles to confirm that they contain eligible trials, with the full text to be reviewed if necessary. Any disagreement during the selection of studies will be discussed and decided by a third author (ZL). Details of the selection process are shown in the PRISMA flow chart (Figure 1).

Data extraction and management

A data extraction form will be used to collect data. A small scope trial will be done before the systematic review is conducted to confirm that there is no obvious divergence between those collecting data. Two authors (XL and YZ) will independently extract the data and take the following aspects into consideration: general information (name and year of publication, date of extraction, title of study, and author's publication details), study characteristics, eligibility criteria, interventions, outcome measurements, duration, adverse events, results, and the type of needle used. All searched studies will be inputted to EndNote software that can assist reviews to manage data and pick up duplicate publications, when two or more publications described a single trial, we included only one report. These data will then be entered into RevMan 5.3.3 software for analysis. Any disagreement will be discussed and finally decided upon by a third author (ZL).

Data items

We will extract the information of each study, including the type of control used, frequency and duration of treatment, patient characteristics (age, gender, duration of symptoms, type of sciatica), trial design, trial size, duration of follow-up, type and source of financial support, if appropriate.

Assessment of risk of bias in included studies

The risk of bias assessment will be based on the Cochrane Collaboration Risk of Bias Tool.^[25]

Two authors (QY and YZ) will independently evaluate methodological quality using the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Other sources of bias may be caused by the different types of needles used, the duration of sciatica, the length of therapy, and the age of patients. Taking these

domains into account, each trial will be categorized into low risk, high risk, and unclear risk. Any disagreements will be discussed and resolved by a third author (ZL).

Confidence in cumulative estimate

Details of acupuncture and control interventions were extracted on the basis of the revised Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)^[26], a checklist that intended for use in conjunction with CONSORT and can estimate randomized controlled trials of acupuncture, include acupuncture rationale, needling details, treatment regimen, co-intervention, control interventions, treating background.

Measurement of treatment effect

Analysis will be based on available data of included studies. For dichotomous data, the risk ratio (RR) will be calculated with 95% confidence intervals (CIs). For continuous variables, means and standard deviations will be used to calculate a mean difference with a 95% CI.

Dealing with missing data

The listed corresponding author will be contacted to try and obtain any missing information from their trial. If it is impossible to obtain the data, the study will be excluded from the data synthesis.

Assessment of heterogeneity

Before combining the statistics, tests for heterogeneity will be used to judge the homogeneity of the studies. If the resulting p value exceeds 0.1, indicating significant heterogeneity among trials, the reasons leading to heterogeneity will be analyzed and subgroup analysis will be conducted.

Assessment of reporting biases

Funnel plot will be used to assess the reporting biases if 10 or more trials are included in a meta-analysis.

Data synthesis

If meta-analysis can be conducted, RevMan V.5.3.3 software will be used to combine the RR with 95% CIs for dichotomous outcomes and the weighted mean difference or standardized mean difference with 95% CIs for continuous data. If the result of the test for heterogeneity

1
2
3 results in $p > 0.1$, the fixed-effect model will be used to combine the data; if $p < 0.1$ the random
4 effect model will be used. If the data will not be suitable for combining quantitatively, in
5 the condition, a systematic narrative synthesis will be provided
6
7 with the information that presented in the text to summarise and explain the
8 characteristics and findings of the included studies.
9

10 11 12 ***Subgroup analysis***

The following subgroup analyses will be conducted to assess the heterogeneity of the studies:

13 14 15 Clinical considerations

- 16 • Acupuncture versus sham acupuncture
- 17 • Types of sciatica (non-discogenic sciatica versus discogenic sciatica)

18 19 20 Methodological considerations

- 21 • Trials with unclear or high risk of bias

22 23 24 ***Sensitivity analysis***

25
26
27 If the test for heterogeneity p value is less than 0.1 after the data extraction has been checked and
28 subgroup analyses conducted, the low-quality studies will be excluded and the meta-analysis
29 will be conducted again.
30
31
32

33 34 35 ***Ethics and dissemination***

36
37 This systematic review will not use data from individual patients to protect privacy, and the
38 results of this systematic review will be disseminated only in a peer-reviewed publication.
39
40
41

42 43 **DISCUSSION**

44
45 Sciatica causes significant suffering for the individual, yet most of the currently available
46 treatment options are not adequate to control pain. Pharmacological methods have associated
47 adverse effects, while surgery is expensive and is not appropriate for every patient. Acupuncture
48 has been used for 3,000 years in China and is generally regarded as a safe and effective measure
49 to alleviate pain. However, when the effectiveness of acupuncture for a condition remains
50 unclear, it is difficult for clinicians to make appropriate recommendations. The mechanism of
51 acupuncture analgesia is gradually becoming known. Han found that acupuncture can promote
52 release of neurotransmitter such as 5-hydroxytryptamine and in addition it generates
53
54
55
56
57
58
59
60

1
2
3 neuropeptide through electrical stimulation of different frequencies that has significantly effect
4 to pain reduction.^[27]
5

6 This is a protocol for a systematic review that aims to assess the safety and effectiveness of
7 acupuncture for sciatica. As there has been no prior systematic review related to acupuncture for
8 sciatica published in English, We hope this systematic review will help clinicians make
9 decisions in practice and promote the progress of acupuncture research.
10

11 This review has some potential limitations. Different forms of acupuncture therapies and
12 quality of methodology in included trials may cause significant heterogeneity. There also may
13 be some relevant studies missed, as only studies published in English, Chinese, and Japanese
14 will be included.
15
16
17
18
19

20 21 22 **Contributors**

23 ZL and ZQ contributed to the conception of the study. The manuscript protocol was drafted by
24 ZQ and revised by QY. The search strategy was developed by all the authors and will be
25 performed by YZ and XL. YZ and XL will also independently screen the potential studies,
26 extract data from the included studies, assess the risk of bias, and complete the data synthesis.
27 ZL will arbitrate in cases of disagreement and ensure the absence of errors. All authors approved
28 the publication of the protocol.
29
30
31
32
33

34 35 36 **Amendments**

37 If it is necessary to amend this protocol we will submit the data of each amendment, the
38 description of change and rationale will be accompanied.
39
40
41

42 43 **Funding statement**

44 This research received no specific grant from any funding agency in the public, commercial, or
45 not-for-profit sectors.
46
47

48
49 **Competing interests:** None.
50
51
52
53
54
55
56
57
58
59
60

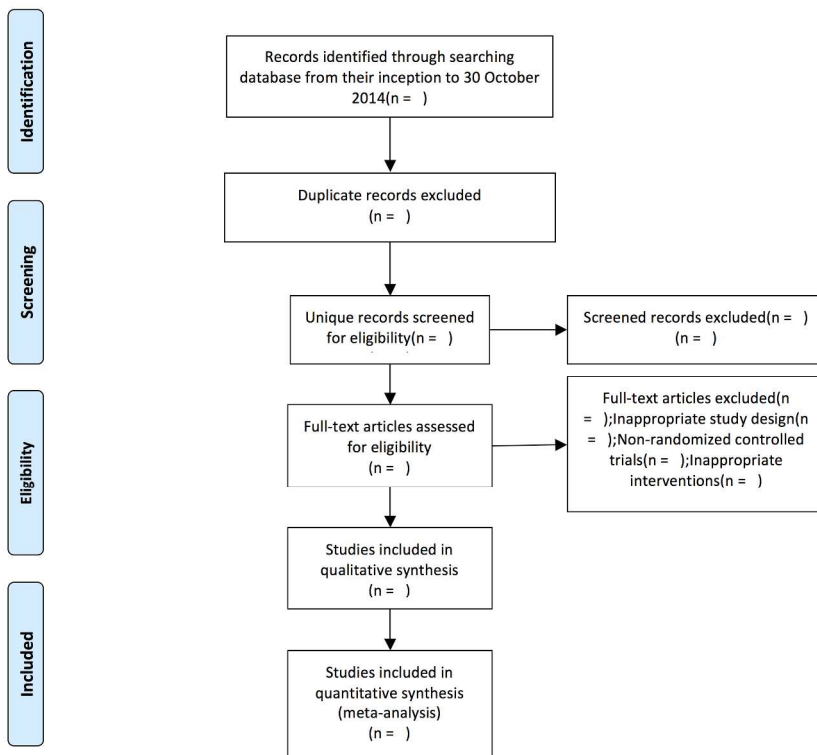
REFERENCES

1. Stafford,M.A., Peng, P., Hill, D.A.,et al., Sciatica: a review of history, epidemiology, pathogenesis, and the role of epidural steroid injection in management. *Br J Anaesth.* 2007;99:461–473.
2. Mathieson, S.,Maher,C.G.,McLachlan,A.J.,et al., *PRECISE - pregabalin in addition to usual care for sciatica: study protocol for a randomised controlled trial.* *Trials*, 2013;14: 213.
3. Frymoyer, J.W., *Lumbar disk disease: epidemiology.* *Instr Course Lect*, 1992;41: 217-23.
4. Frymoyer, J.W., *Back pain and sciatica.* *N Engl J Med*, 1988; 318: 291-300.
5. Konstantinou, K. and K.M. Dunn.,*Sciatica: review of epidemiological studies and prevalence estimates.* *Spine* 2008;33: 2464-72.
6. Younes, M.,Bejia,I.,Aguir,Z.,et al., *Prevalence and risk factors of disk-related sciatica in an urban population in Tunisia.* *Joint Bone Spine*, 2006;73:538-42.
7. Weber, H., I. Holme, and E. Amlie.,*The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam.* *Spine*, 1993;18:1433-8.
8. Lewis,R.A.,Willams,N.H.,Sutton,A.J.,et al., *Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses.* *Spine J.* Epub October 4, 2013.
9. Valat, J.P., Giraudeau,B.,Rozenberg,S.,et al., *Epidural corticosteroid injections for sciatica: a randomised, double blind, controlled clinical trial.* *Ann Rheum Dis* 2003;62: 639-43.
10. Carette, S., Leclaire,R.,Marcoux,S.,et al., *Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus.* *N Engl J Med* 1997;336 :1634-40.
11. Finckh,A.,Zufferey,P.,Schurch,M.A.,et al., *Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial.* *Spine* 2006;31: 377-81.
12. Korhonen,T., Karppinen,J.,Paimela,L.,et al., *The treatment of disc herniation-induced sciatica with infliximab: results of a randomized, controlled, 3-month follow-up study.* *Spine* 2005;30: 2724-8.
13. Atlas, S.J., Keller,R.B.,WU,Y.A.,et al., *Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the maine lumbar spine study.* *Spine* 2005;30: 936-43.
14. Legrand, E., Bouvard,B.,Audran,M.,et al., *Sciatica from disk herniation: Medical treatment or*

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- surgery? *Joint Bone Spine* 2007; **74**: 530-535.
15. Van Tulder MW., Koes B., Seitsalo S., et al., *Outcome of invasive treatment modalities on back pain and sciatica: an evidence-based review*. *Eur Spine J.* 2006;15:S82–S92.
16. Lee JH., Choi TY., Lee MS., et al., *Acupuncture for acute low back pain: a systematic review*. *Clin J Pain* 2013, 29:172–185.
17. Iannuccelli,C., Mannocci,F., Guzzo,M.P.,et al., *Complementary treatment in fibromyalgia: combination of somatic and abdominal acupuncture*. *Clin Exp Rheumatol* 2012, 30:112–116
18. Witt,C., Brinkhaus,B., Jena,S., et al.,*Acupuncture in patients with osteoarthritis of the knee: a randomised trial*. *Lancet* 2005, 366:136–143.
19. Duplan,B., Cabanel,G,Piton,J.L.,et al., *Acupuncture and sciatica in the acute phase. Double-blind study of 30 cases*. *Sem Hop* 1983; **59**: 3109-14.
20. Zhang, P., *Essentials for the acupuncture treatment of radicular sciatica*. *J Tradit Chin Med* 2003;**23**: 237.
21. Li, J., J.C. Dong, and J.J. Yue., *Effects of acupuncture on default mode network images of chronic sciatica patients in the resting network state*. *Zhongguo Zhong Xi Yi Jie He Za Zhi* 2012;**32**: 1624-7.
22. Chen, M.R., Wang,P.,Cheng,G.,et al., *The warming acupuncture for treatment of sciatica in 30 cases*. *J Tradit Chin Med* 2009; **29**: 50-3.
23. Wang BX, La JL., *Therapeutic effects of electro-acupuncture and diclofenic on herniation of lumbar intervertebral disc*. *Zhongguo Linchuang Kangfu* 2004;8:3413-5.
24. Higgins,J.P., Green,S., *Cochrane handbook for systematic reviews of interventions version 5.1*. 0 [updated March 2011]. The Cochrane Collaboration, 2011.
25. Higgins,J.P., Altman,D.G., Gotzsche,P.C.,et al.,Cochrane Bias Methods Group; Cochrane Statistical Methods Group: *The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials*. *BMJ* 2011, 343:d5928.
26. MacPherson,H.,Altman,DG., Hammerschlag,R.,et al., *Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement*. *PLoS Med.* 2010;7:e1000261
27. Han, J.S., *Acupuncture:neuropeptide release produced by electrical stimulation of different frequencies*. *Trends in Neuroscience* 2003;**26**: 17-22.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1 Study flow diagram.



215x279mm (300 x 300 DPI)

table 1 Search strategy used in PubMed database

No.	Search Items
1.	randomized controlled trial.pt
2.	controlled clinical trial.pt
3.	randomized.ti,ab
4.	randomly.ti,ab
5.	groups.ti,ab
6.	trial.ti,ab
7.	or 1-6
8.	acupuncture.ti,ab
9.	electro-acupuncture.ti,ab
10.	elongated needle.ti,ab
11.	three edged needle.ti,ab
12.	(fire needle or warming needle).ti,ab
13.	auricular acupuncture.ti,ab
14.	abdominal acupuncture.ti,ab
15.	warm acupuncture.ti,ab
16.	pyonex.ti,ab
17.	or 8-16
18.	sciatica.ti,ab
19.	sciatic neuralgia.ti,ab
20.	discogenic sciatica.ti,ab
21.	bilateral sciatica.ti,ab
22.	disc herniation-induced sciatica.ti,ab
23.	or 18-22
24.	7 and 17 and 23

This search strategy will be modified as required for other electronic databases.

Table S1
PRISMA-P checklist

Section and topic	Item No.	checklist item
Administrative information		
Title		
Identification	1a	Acupuncture for sciatica: a systematic review protocol (p1)
Update	1b	None
Registration	2	In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPER) on 20 November 2014 (registration number CRD42014015001) (p2)
Authors		
Contact	3a	Corresponding author: Zhi-shun Liu Email: liuzhishun@aliyun.com Author Affiliations 1. Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China 2. Graduate School, Beijing University of Chinese Medicine, Beijing 100029, China Email: 1471911071@qq.com (Zongshi Qiu) liuzhishun_liu@163.com (Xiaoan Liu) 1126873424@qq.com (Qin Yao) 746475225@qq.com (Yanbin Zhai) (p1)
Contributions	3b	ZL and ZQ contributed to the conception of the study. The manuscript protocol was drafted by ZQ and revised by QY. The search strategy was developed by all the authors and will be performed by YZ and XL. YZ and XL will independently screen the potential studies, extract data from the included studies, assess the risk of bias, and complete the data synthesis. ZL will arbitrate in cases of disagreement and ensure the absence of errors. All authors approved the publication of the protocol (p9)
Amendments	4	If it is necessary to amend this protocol we will submit the data of each amendment, the description of change and rationale will be accompanied (p9)
Support		
Sources	5a	This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors (p9)
Sponsor	5b	None
Role of sponsor or funder	5c	None
Introduction		
Rationale	6	Sciatica is a common neuropathy characterized by pain radiating into the leg; it is usually caused by nerve root compression and irritation or inflammation of the sciatic nerve, and is often accompanied by lower back pain and neurological deficits in the lower limb. The pain is often associated with tingling, numbness, and weakness of the leg; it may be sudden in onset and then persist for days or weeks. Frymoyer reported that sciatica is very common, with a lifetime incidence varying from 13% to 40% and a corresponding annual incidence of sciatica episodes of 1–5%. Sciatica commonly affects people between the ages of 30 and 50 years, with the pain of sciatica significantly damaging health. Thus, according to the reporting of Younes M, in Tunisia sciatica has become a major cause of work absenteeism and a financial burden to society. Previous research has reported that 60% of patients with sciatica will have a mild disability and based on questionnaires at months 3 and 12 there is a 30% of patients that live with sciatica for more than 1 year, which results in an obvious decrease in quality of life. The current management of sciatica can be classified into pharmacological and non-pharmacological treatment. One reporting supports the effectiveness of nonopioid medication, epidural injections, and disc surgery. It also suggests that spinal manipulation, acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be considered. The use of pharmacological products such as anesthetics or corticosteroids has associated adverse effects including sedation, dizziness, ataxia, and nausea, and their effectiveness decreases with long-term use. Although according to the prior systematic review epidural injections has better effect for pain reduction than nonopioids, related adverse effects to epidural injections have been reported. To date, there is no strong evidence-based medicine proving that non-pharmacological conservative treatment of Western medicine is effective; and surgical procedures are invasive, expensive, and may cause neurological complications. Currently, sciatica is one of the primary reasons for hospital consultations. Acupuncture has become a widely used method for treating sciatica in many countries, including China, the USA, and Japan. Acupuncture is reported to be effective in treating many types of musculoskeletal pain including lower back pain, fibromyalgia, osteoarthritis, and sciatica. However, the ability of acupuncture to successfully manage sciatica, either as a monotherapy or as an adjunct to Western medical care, remains unclear. This systematic review aims to assess the efficacy and safety of acupuncture for treating sciatica, with the resulting evaluation aiming to help clinicians make decisions on treating sciatica, and to help patients seeking further treatment options. (p2)
Objectives	7	The aim of this systematic review is to evaluate the effectiveness and safety of acupuncture in the management of sciatica for the patients. To this end, we will pose the two questions: What is the comparative efficacy and safety of acupuncture compared to sham acupuncture, anal care, or no treatment to reduce pain intensity in patients diagnosed with sciatica? Is there a definitive advantage of acupuncture compared with western medication? (p4)
Methods		
Eligibility criteria	8	Types of participants Patients with sciatica will be included, including those diagnosed with sciatica syndromes such as radiculopathy, nerve root compromise, nerve root compression, nerve root pain, and pain radiating below the knee. There will be no restriction on sex, age, or the intensity or duration of symptoms. Patients with acute infection, caudal equina syndrome, primary spinal stenosis, and lower back pain without sciatica will be excluded. Types of interventions Any type of invasive acupuncture will be included, such as acupuncture, electro-acupuncture, elongated needle acupuncture, three-edged needle acupuncture, fire needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and pyonex. Control interventions may include general care, sham acupuncture/placebo, and waiting list care. - Acupuncture versus other Western medicine treatment will be included. - Acupuncture plus another Western medicine treatment versus the same Western medicine treatment alone will be included. - RCTs comparing two different types of acupuncture will be excluded. - Acupuncture treatment without needle insertion (e.g., acupressure, laser acupuncture, and electrical stimulation) will be excluded. - Acupuncture combined with Chinese medicine, acupoint injection, and/or needle knife will be excluded. Types of outcome assessments Primary outcomes: - Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)). - Global assessment (the proportion of patients improved or cured). Secondary outcomes: - Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form health survey (SF-36) - Physical examinations. - Patient satisfaction. - Adverse effects (p5)
Information sources	9	A search strategy will be used and conducted according to the Cochrane handbook guidelines. The following nine databases will be searched from their inception to 30 October 2014: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics (CINI). The search strategy is based on the guidance of the Cochrane handbook. The key words include: "sciatica", "sciatic neuralgia", "disogenic sciatica", "disc herniation-induced sciatica", "bilateral sciatica", "acupuncture", "electro-acupuncture", "elongated needle", "three-edged needle", "fire needling", "auricular acupuncture", "abdominal acupuncture", and "pyonex" (p5)
Search strategy	10	This search strategy will also be applied to the other electronic databases. Search strategy used in PubMed database 1. randomized controlled trial pt 2. controlled clinical trial pt 3. randomized ti,ab 4. randomly ti,ab 5. groups ti,ab 6. trial ti,ab 7. or 1-6 8. acupuncture ti,ab 9. electro-acupuncture ti,ab 10. elongated needle ti,ab 11. three edged needle ti,ab 12. fire needle or warming needle ti,ab 13. auricular acupuncture ti,ab 14. abdominal acupuncture ti,ab 15. warm acupuncture ti,ab 16. pyonex ti,ab 17. or 8-16 18. sciatica ti,ab 19. sciatic neuralgia ti,ab 20. disogenic sciatica ti,ab 21. bilateral sciatica ti,ab 22. disc herniation-induced sciatica ti,ab 23. or 18-22 24. 7 and 17 and 23 (p12)
Study records:		
Data management	11a	All searched studies will be imported to EndNote software that can assist reviews to manage data and pick up duplicate publications, when two or more publications described a single trial, we included only one report. (p6)
Selection process	11b	Two authors (XL and YZ) will screen the title and abstracts of all the articles to confirm that they contain eligible trials, with the full text to be reviewed if necessary. Any disagreement during the selection of studies will be discussed and decided by a third author (ZL). Details of the selection process are shown in the PRISMA flow chart (Figure 1) (p6)
Data collection process	11c	A data extraction form will be used to collect data. A small scope trial will be done before the systematic review is conducted to confirm that there is no obvious divergence between those collecting data. Two authors (XL and YZ) will independently extract the data and take the following aspects into consideration: general information (name and year of publication, date of extraction, title of study, and author's publication details), study characteristics, eligibility criteria, interventions, outcome measurements, duration, adverse events, results, and the type of needle used. These data will then be entered into RevMan 5.3.3 software for analysis. Any disagreement will be discussed and finally decided upon by a third author (ZL). (p6)
Data items	12	We will extract the information of each study, including the type of control used, frequency and duration of treatment, patient characteristics (age, gender, duration of symptoms, type of sciatica), trial design, trial size, duration of follow-up, type and source of financial support, if appropriate. (p6)
Outcomes and prioritization	13	Primary outcomes: - Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)). - Global assessment (the proportion of patients improved or cured). Secondary outcomes: - Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form health survey (SF-36) - Physical examinations. - Patient satisfaction. - Adverse effects (p5)
Risk of bias in individual studies	14	The risk of bias assessment will be based on the Cochrane Collaboration Risk of Bias Tool. Two authors (QY and YZ) will independently evaluate methodological quality using the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Other sources of bias may be caused by the different types of needles used, the duration of sciatica, the length of therapy, and the age of patients. Taking these domains into account, each trial will be categorized into low risk, high risk, and unclear risk. Any disagreements will be discussed and resolved by a third author (ZL). (p6-7)
Data synthesis	15a	If meta-analysis can be conducted, RevMan 5.3.3 software will be used to combine the RR with 95% CIs for dichotomous outcomes and the weighted mean difference or standardized mean difference with 95% CIs for continuous data. If the result of the test for heterogeneity results in $p > 0.1$, the fixed-effect model will be used to combine the data; if $p < 0.1$, the random effect model will be used. (p8)
	15b	Analysis will be based on available data of included studies. For dichotomous data, the risk ratio (RR) will be calculated with 95% confidence intervals (CIs). For continuous variables, means and standard deviations will be used to calculate a mean difference with a 95% CI. (p8)
	15c	The following subgroup analyses will be conducted to assess the heterogeneity of the studies: Clinical considerations: - Acupuncture versus sham acupuncture - Types of sciatica (non-disogenic sciatica versus disogenic sciatica) Methodological considerations: - Trials with unclear or high risk of bias (p8)
	15d	If the data will not be suitable for combining quantitatively, in the condition, a systematic narrative synthesis will be provided with the information that presented in the text to summarise and explain the characteristics and findings of the included studies. (p8)
Meta-bias	16	Funnel plot will be used to assess the reporting biases if 10 or more trials are included in a meta-analysis. (p7)
Confidence in cumulative estimate	17	Details of acupuncture and control interventions were extracted on the basis of the revised Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA), a checklist that intended for use in conjunction with CONSORT and can estimate randomized controlled trials of acupuncture, include acupuncture rationale, needling details, treatment regimen, co-intervention, control interventions, treating background. (p7)

BMJ Open

Acupuncture for treating sciatica: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-007498.R2
Article Type:	Protocol
Date Submitted by the Author:	05-Mar-2015
Complete List of Authors:	Qin, ZongShi; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Xiaoxu; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Yao, Qin; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Zhai, Yanbing; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture Liu, Zhishun; Guang'anmen Hospital,China Academy of Chinese Medical Sciences, Department of Acupuncture
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	Evidence based practice, Neurology, Medical publishing and peer review
Keywords:	COMPLEMENTARY MEDICINE, Neurological pain < NEUROLOGY, Neuropathology < NEUROLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PAIN MANAGEMENT

SCHOLARONE™
Manuscripts

only

Acupuncture for treating sciatica: a systematic review protocol

Zongshi Qin,^{1,2} Xiaoxu Liu,^{1,2} Qin Yao,^{1,2} Yanbin Zhai,^{1,2} Zhishun Liu^{1*}

¹Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China

² Beijing University of Chinese Medicine, Beijing 100029, China

*Correspondence to: Professor Zhishun Liu, Tel.: 86-10-88001124, E-mail: liuzhishun@aliyun.com

Running title: Acupuncture for sciatica: a systematic review protocol

Key words: acupuncture, sciatica, systematic review, protocol

Word count: 2,578

ABSTRACT

Introduction: This systematic review aims to assess the effectiveness and safety of acupuncture for treating sciatica.

Methods: The following nine databases will be searched from their inception to 30 October 2014: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics (CiNii). Randomized controlled trials of acupuncture for sciatica in English, Chinese, or Japanese without restriction of publication status will be included. Two researchers will independently undertake study selection, extraction of data, and assessment of study quality. Meta-analysis will be conducted after screening of studies. Data will be analyzed using risk ratio for dichotomous data, and standardized mean difference or weighted mean difference for continuous data.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Dissemination: This systematic review will be disseminated electronically through peer-reviewed publication or conference presentations.

Trial registration number: PROSPERO CRD42014015001

Strengths and limitations of this study

- The effectiveness of conservative therapy for sciatica is uncertain, and acupuncture may provide an effective alternative treatment method. To the best of the authors' knowledge, there is currently no systematic review published in English related to acupuncture for sciatica. The results of this systematic review will help clinicians make decisions on treating sciatica, and help patients seeking further treatment options.
- One limitation of this systematic review is that because of the language barrier, trials in only three languages can be included. Hence, relevant studies published in other languages might be missed.
- Another limitation is that the different forms of acupuncture therapy and quality of methodologies in the included studies may cause significant heterogeneity.

INTRODUCTION

Sciatica is a common neuralgia characterized by pain radiating into the leg; it is usually caused by nerve root compression and irritation or inflammation of the sciatic nerve, and is often accompanied by lower back pain and neurological deficits in the lower limb.^[1] The pain is often associated with tingling, numbness, and weakness of the leg; it may be sudden in onset and then persist for days or weeks.^[2] Frymoyer reported that sciatica is very common, with a lifetime incidence varying from 13% to 40% and a corresponding annual incidence of sciatica episodes of 1–5%.^[3,4]

Sciatica commonly affects people between the ages of 30 and 50 years, with the pain of sciatica significantly damaging health.^[5] Thus, according to the reporting of Younes.M, in Tunisia sciatica has become a major cause of work absenteeism and a financial burden to society.^[6] Previous research has indicated that 60% of patients with sciatica suffer from a mild disability. Based on questionnaires (given at the third through twelfth month of symptom exhibition), 30% of patients live with sciatica for more than 1 year, which results in an obvious decrease in quality of life.^[7] The current management of sciatica can be classified into pharmacological and non-pharmacological treatment. One article supports the effectiveness of nonopioid medication, epidural injections, and disc surgery. It also suggests that spinal manipulation, acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be considered.^[8] The use of pharmacological products such as anesthetics or corticosteroids has associated adverse effects including sedation, dizziness, ataxia, and nausea, and their effectiveness decreases with long-term use.^[9] Although according to the prior systematic review epidural injections has better effect for pain reduction than nonopioids,^[8] related adverse effects to epidural injections have been reported.^[10-12] To date, there is no strong evidence-based medicine proving that non-pharmacological conservative treatment of Western medicine is effective^[13,14], and surgical procedures are invasive, expensive, and may cause neurological complications.^[15]

In China, sciatica is a primary cause for hospitalization and it is commonly used for managing neuralgia pain.^[16] Acupuncture is reported to be effective in treating many types of musculoskeletal pain including lower back pain,^[17] fibromyalgia,^[18] osteoarthritis,^[19] and sciatica.^[20-24] However, the ability of acupuncture to successfully manage sciatica, either as a monotherapy or as an adjunct to Western medical care, remains unclear.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

This systematic review aims to assess the effectiveness and safety of acupuncture for treating sciatica. To this end, we will pose the following question: What is the comparative effectiveness and safety of acupuncture compared to sham acupuncture, usual care, or no treatment to reduce pain intensity in patients diagnosed with sciatica? Is there a definitive advantage of acupuncture compared with western medication? With the resulting evaluation aiming to help clinicians make decisions on treating sciatica, and to help patients seeking further treatment options.

METHODS AND ANALYSIS

Criteria for inclusion of studies in this review:

Types of studies

Only randomized controlled trials (RCTs) will be included; quasi-RCTs and randomized crossover studies will be excluded. Blinding will not be considered because of the characteristics of acupuncture treatment.

Types of participants

Patients with sciatica will be included, including those diagnosed with sciatica synonyms such as radiculopathy, nerve root compromise, nerve root compression, nerve root pain, and pain radiating below the knee. There will be no restriction on sex, age, or the intensity or duration of symptoms.

Patients with acute infection, caudal equina syndrome, primary spinal stenosis, and lower back pain without sciatica will be excluded.

Types of interventions

- Any type of invasive acupuncture will be included, such as acupuncture, electro-acupuncture, elongated needle acupuncture, three-edged needle acupuncture, fire needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and pyonex. Control interventions may include general care, sham acupuncture/placebo, and waiting list care.
- Acupuncture versus other Western medicine treatment will be included.
- Acupuncture plus another Western medicine treatment versus the same Western medicine treatment alone will be included.
- RCTs comparing two different types of acupuncture will be excluded.
- Acupuncture treatment without needle insertion (e.g., acupressure, laser acupuncture, and

1
2
3 electrical stimulation) will be excluded.

- 4
5 • Acupuncture combined with Chinese medicine, acupoint injection, and/or needle knife will
6 be excluded.
7
8
9

10 **Types of outcome assessments**

11 Primary outcomes:

- 12
13 • Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale
14 (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)).
15
16 • Global assessment (the proportion of patients improved or cured).
17
18

19 Secondary outcomes:

- 20
21 • Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form
22 health survey (SF-36)
23
24 • Physical examinations.
25
26 • Patient satisfaction.
27
28 • Adverse effects.
29

30 **Search methods for identification of studies**

31 A search strategy will be used and conducted according to the Cochrane handbook guidelines.

32 [25] The following nine databases will be searched from their inception to 30 October 2014:

33 MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL),
34 Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC),
35 Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National
36 Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics
37 (CiNii). The search strategy is based on the guidance of the Cochrane handbook. The key words
38 include “sciatica”, “sciatic neuralgia”, “discogenic sciatica”, “disc herniation-induced sciatica”,
39 “bilateral sciatica”, “acupuncture”, “electro-acupuncture”, “elongated needle”, “three-edged
40 needle”, “fire needling”, “auricular acupuncture”, “abdominal acupuncture”, and “pyonex”.
41
42
43
44
45
46
47
48
49

50 The strategy for searching the PUBMED database is shown in Table 1. This search strategy will
51 also be applied to the other electronic databases.
52
53
54

55 **Data collection and analysis**

56 *Selection of studies*

57
58
59
60

1
2
3 Two authors (XL and YZ) will screen the title and abstracts of all the articles to confirm that they
4 contain eligible trials, with the full text to be reviewed if necessary. Any disagreement during the
5 selection of studies will be discussed and decided by a third author (ZL). Details of the selection
6 process are shown in the PRISMA flow chart (Figure 1).
7
8
9

10 11 ***Data extraction and management***

12 A data extraction form will be used to collect data. A small scope trial will be done before the
13 systematic review is conducted to confirm that there is no obvious divergence between those
14 collecting data. Two authors (XL and YZ) will independently extract the data and take the
15 following aspects into consideration: general information (name and year of publication, date of
16 extraction, title of study, and author's publication details), study characteristics, eligibility
17 criteria, interventions, outcome measurements, duration, adverse events, results, and the type of
18 needle used. All searched studies will be inputted to EndNote software that can assist reviews to
19 manage data and pick up duplicate publications, when two or more publications described a
20 single trial, we included only one report. These data will then be entered into RevMan 5.3.3
21 software for analysis. Any disagreement will be discussed and finally decided upon by a third
22 author (ZL).
23
24
25
26
27
28
29
30
31
32

33 ***Data items***

34 We will extract the information of each study, including the type of control used, frequency and
35 duration of treatment, patient characteristics (age, gender, duration of symptoms, type of
36 sciatica), trial design, trial size, duration of follow-up, type and source of financial support, if
37 appropriate.
38
39
40
41
42
43

44 ***Assessment of risk of bias in included studies***

45 The risk of bias assessment will be based on the Cochrane Collaboration Risk of Bias Tool.^[26]
46 Two authors (QY and YZ) will independently evaluate methodological quality using the
47 following seven domains: random sequence generation, allocation concealment, blinding of
48 participants and personnel, blinding of outcome assessment, incomplete outcome data, selective
49 reporting, and other bias. Other sources of bias may be caused by the different types of needles
50 used, the duration of sciatica, the length of therapy, and the age of patients. Taking these
51 domains into account, each trial will be categorized into low risk, high risk, and unclear risk.
52 Any disagreements will be discussed and resolved by a third author (ZL).
53
54
55
56
57
58
59
60

Confidence in cumulative estimate

Details of acupuncture and control interventions were extracted on the basis of the revised Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)^[27], a checklist that intended for use in conjunction with CONSORT and can estimate randomized controlled trials of acupuncture, include acupuncture rationale, needling details, treatment regimen, co-intervention, control interventions, treating background.

Measurement of treatment effect

Analysis will be based on available data of included studies. For dichotomous data, the risk ratio (RR) will be calculated with 95% confidence intervals (CIs). For continuous variables, means and standard deviations will be used to calculate a mean difference with a 95% CI.

Dealing with missing data

The listed corresponding author will be contacted to try and obtain any missing information from their trial. If it is impossible to obtain the data, the study will be excluded from the data synthesis.

Assessment of heterogeneity

Before combining the statistics, tests for heterogeneity will be used to judge the homogeneity of the studies. If the resulting p value exceeds 0.1, indicating significant heterogeneity among trials, the reasons leading to heterogeneity will be analyzed and subgroup analysis will be conducted.

Assessment of reporting biases

Funnel plot will be used to assess the reporting biases if 10 or more trials are included in a meta-analysis.

Data synthesis

If meta-analysis can be conducted, RevMan V.5.3.3 software will be used to combine the RR with 95% CIs for dichotomous outcomes and the weighted mean difference or standardized mean difference with 95% CIs for continuous data. If the result of the test for heterogeneity results in $p > 0.1$, the fixed-effect model will be used to combine the data; if $p < 0.1$ the random effect model will be used. If the data will not be suitable for combining quantitatively, in

1
2
3 the condition, a systematic narrative synthesis will be provided
4
5 with the information that presented in the text to summarise and explain the
6
7 characteristics and findings of the included studies.
8
9

10 ***Subgroup analysis***

11 The following subgroup analyses will be conducted to assess the heterogeneity of the studies:

12 Clinical considerations

- 13 • Acupuncture versus sham acupuncture
- 14 • Types of sciatica (non-discogenic sciatica versus discogenic sciatica)

15 Methodological considerations

- 16 • Trials with unclear or high risk of bias

17 ***Sensitivity analysis***

18 If the test for heterogeneity p value is less than 0.1 after the data extraction has been checked and
19
20 subgroup analyses conducted, the low-quality studies will be excluded and the meta-analysis
21
22 will be conducted again.
23
24

25 ***Ethics and dissemination***

26 This systematic review will not use data from individual patients to protect privacy, and the
27
28 results of this systematic review will be disseminated only in a peer-reviewed publication.
29
30
31

32 **DISCUSSION**

33
34 Sciatica causes significant suffering for the individual, yet most of the currently available
35
36 treatment options are not adequate to control pain. Pharmacological methods have associated
37
38 adverse effects, while surgery is expensive and is not appropriate for every patient. Acupuncture
39
40 has been used for 3,000 years in China and is generally regarded as a safe and effective measure
41
42 to alleviate pain. However, when the effectiveness of acupuncture for a condition remains
43
44 unclear, it is difficult for clinicians to make appropriate recommendations. The mechanism of
45
46 acupuncture analgesia is gradually becoming known. Han found that acupuncture can promote
47
48 release of neurotransmitter such as 5-hydroxytryptamine and in addition it generates
49
50 neuropeptide through electrical stimulation of different frequencies that has significantly effect
51
52 to pain reduction.^[28]
53
54
55
56
57
58
59
60

1
2
3 This is a protocol for a systematic review that aims to assess the safety and effectiveness of
4 acupuncture for sciatica. As there has been no prior systematic review related to acupuncture for
5 sciatica published in English, We hope this systematic review will help clinicians make
6 decisions in practice and promote the progress of acupuncture research.
7
8

9
10 This review has some potential limitations. Different forms of acupuncture therapies and
11 quality of methodology in included trials may cause significant heterogeneity. There also may
12 be some relevant studies missed, as only studies published in English, Chinese, and Japanese
13 will be included.
14
15

16 17 18 19 **Contributors**

20 ZL and ZQ contributed to the conception of the study. The manuscript protocol was drafted by
21 ZQ and revised by QY. The search strategy was developed by all the authors and will be
22 performed by YZ and XL. YZ and XL will also independently screen the potential studies,
23 extract data from the included studies, assess the risk of bias, and complete the data synthesis.
24 ZL will arbitrate in cases of disagreement and ensure the absence of errors. All authors approved
25 the publication of the protocol.
26
27
28
29
30
31

32 33 **Acknowledgement**

34 At the point of finishing this paper, I'd like to express my sincere thanks to all those who have
35 lent me helping hands over the course of writing this paper, I'd like to take this opportunity to
36 show my sincere gratitude to my friend, Mr. Brendan Melchiorri, who has given me so much
37 useful advice on my writing, and has tried his best to improve my paper.
38
39
40
41

42 43 **Amendments**

44 If it is necessary to amend this protocol we will submit the data of each amendment, the
45 description of change and rationale will be accompanied.
46
47
48

49 50 **Funding statement**

51 This research received no specific grant from any funding agency in the public, commercial, or
52 not-for-profit sectors.
53

54 **Competing interests:** None.
55
56

57 58 **REFERENCES** 59 60

1. Stafford, M.A., Peng, P., Hill, D.A., et al., Sciatica: a review of history, epidemiology, pathogenesis, and the role of epidural steroid injection in management. *Br J Anaesth.* 2007;99:461–473.
2. Mathieson, S., Maher, C.G., McLachlan, A.J., et al., *PRECISE - pregabalin in addition to usual care for sciatica: study protocol for a randomised controlled trial.* *Trials*, 2013;14: 213.
3. Frymoyer, J.W., *Lumbar disk disease: epidemiology.* *Instr Course Lect*, 1992;41: 217-23.
4. Frymoyer, J.W., *Back pain and sciatica.* *N Engl J Med*, 1988; 318: 291-300.
5. Konstantinou, K. and K.M. Dunn., *Sciatica: review of epidemiological studies and prevalence estimates.* *Spine* 2008;33: 2464-72.
6. Younes, M., Bejjia, I., Aguir, Z., et al., *Prevalence and risk factors of disk-related sciatica in an urban population in Tunisia.* *Joint Bone Spine*, 2006;73:538-42.
7. Weber, H., I. Holme, and E. Amlie., *The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam.* *Spine*, 1993;18:1433-8.
8. Lewis, R.A., Willams, N.H., Sutton, A.J., et al., *Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses.* *Spine J.* Epub October 4, 2013.
9. Valat, J.P., Giraudeau, B., Rozenberg, S., et al., *Epidural corticosteroid injections for sciatica: a randomised, double blind, controlled clinical trial.* *Ann Rheum Dis* 2003;62: 639-43.
10. Carette, S., Leclaire, R., Marcoux, S., et al., *Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus.* *N Engl J Med* 1997;336 :1634-40.
11. Finckh, A., Zufferey, P., Schurch, M.A., et al., *Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial.* *Spine* 2006;31: 377-81.
12. Korhonen, T., Karppinen, J., Paimela, L., et al., *The treatment of disc herniation-induced sciatica with infliximab: results of a randomized, controlled, 3-month follow-up study.* *Spine* 2005;30: 2724-8.
13. Atlas, S.J., Keller, R.B., Wu, Y.A., et al., *Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the maine lumbar spine study.* *Spine* 2005;30: 936-43.
14. Legrand, E., Bouvard, B., Audran, M., et al., *Sciatica from disk herniation: Medical treatment or surgery?* *Joint Bone Spine* 2007; 74: 530-535.

15. Van Tulder MW., Koes B., Seitsalo S., et al., *Outcome of invasive treatment modalities on back pain and sciatica: an evidence-based review*. Eur Spine J. 2006;15:S82–S92.
16. Wang,S.Z.,Wu,G.Y.,Huang,Y., et al., *Integrated traditional Chinese and western medicine treatment overview for sciatica*. HuNan Journal of traditional Chinese medicine 2014,30;133-134
17. Lee JH., Choi TY., Lee MS.,et al., *Acupuncture for acute low back pain: a systematic review*. Clin J Pain 2013, 29:172–185.
18. Iannuccelli,C., Mannocci,F., Guzzo,M.P.,et al., *Complementary treatment in fibromyalgia: combination of somatic and abdominal acupuncture*. Clin Exp Rheumatol 2012, 30:112–116
19. Witt,C., Brinkhaus,B., Jena,S., et al.,*Acupuncture in patients with osteoarthritis of the knee: a randomised trial*. Lancet 2005, 366:136–143.
20. Duplan,B., Cabanel,G,Piton,J.L.,et al., *Acupuncture and sciatica in the acute phase. Double-blind study of 30 cases*. Sem Hop 1983; **59**: 3109-14.
21. Zhang, P., *Essentials for the acupuncture treatment of radicular sciatica*. J Tradit Chin Med 2003;**23**: 237.
22. Li, J., J.C. Dong, and J.J. Yue., *Effects of acupuncture on default mode network images of chronic sciatica patients in the resting network state*. Zhongguo Zhong Xi Yi Jie He Za Zhi 2012;**32**: 1624-7.
23. Chen, M.R., Wang,P,Cheng,G,et al., *The warming acupuncture for treatment of sciatica in 30 cases*. J Tradit Chin Med 2009; **29**: 50-3.
24. Wang BX, La JL., *Therapeutic effects of electro-acupuncture and diclofenic on herniation of lumbar intervertebral disc*. Zhongguo Linchuang Kangfu 2004;8:3413-5.
25. Higgins,J.P., Green,S., *Cochrane handbook for systematic reviews of interventions version 5.1*. 0 [updated March 2011]. The Cochrane Collaboration, 2011.
26. Higgins,J.P., Altman,D.G., Gotzsche,P.C.,et al.,*Cochrane Bias Methods Group; Cochrane Statistical Methods Group: The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials*. BMJ 2011, 343:d5928.
27. MacPherson,H.,Altman,DG., Hammerschlag,R.,et al., *Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement*. PLoS Med. 2010;7:e1000261
28. Han, J.S., *Acupuncture:neuropeptide release produced by electrical stimulation of different frequencies*. Trends in Neuroscience 2003;**26**: 17-22.

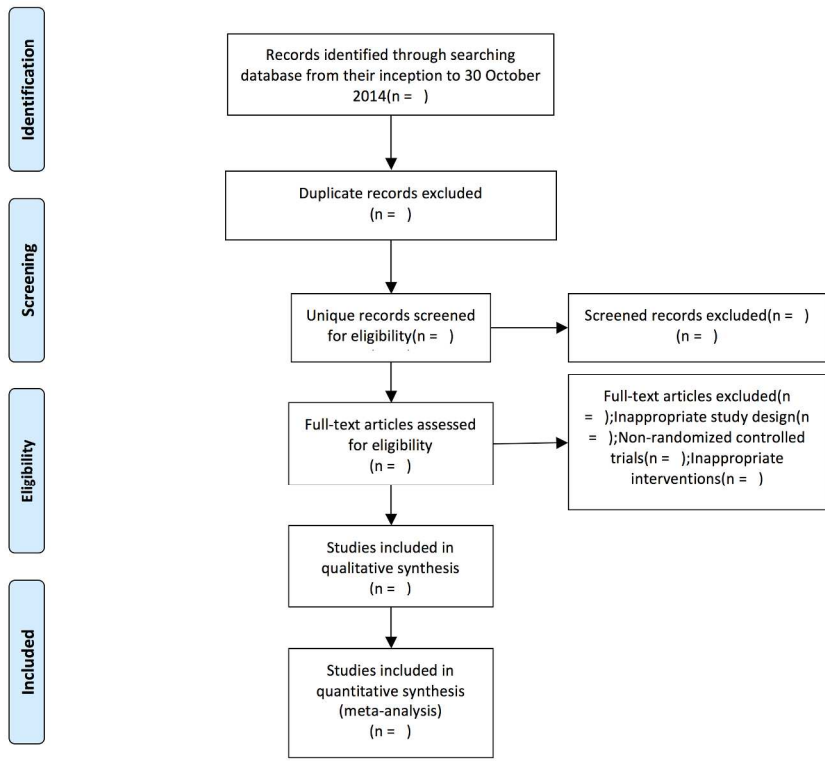
table 1 Search strategy used in PubMed database

No.	Search Items
1.	randomized controlled trial.pt
2.	controlled clinical trial.pt
3.	randomized.ti,ab
4.	randomly.ti,ab
5.	groups.ti,ab
6.	trial.ti,ab
7.	or 1-6
8.	acupuncture.ti,ab
9.	electro-acupuncture.ti,ab
10.	elongated needle.ti,ab
11.	three edged needle.ti,ab
12.	(fire needle or warming needle).ti,ab
13.	auricular acupuncture.ti,ab
14.	abdominal acupuncture.ti,ab
15.	warm acupuncture.ti,ab
16.	pyonex.ti,ab
17.	or 8-16
18.	sciatica.ti,ab
19.	sciatic neuralgia.ti,ab
20.	discogenic sciatica.ti,ab
21.	bilateral sciatica.ti,ab
22.	disc herniation-induced sciatica.ti,ab
23.	or 18-22
24.	7 and 17 and 23

This search strategy will be modified as required for other electronic databases.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1 Study flow diagram.



215x279mm (300 x 300 DPI)

Supplemental File 1

PRISMA-P checklist

Section and topic	Item No.	checklist item
Administrative information		
Title	1a	Acupuncture for sciatica: a systematic review protocol (p1)
Identification	1b	None
Update	2	In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPER) on 20 November 2014 (registration number CRD42014015001) (p2)
Registration		
Authors	3a	Corresponding author: Zhi-shun Liu Email: liuzhishun@aliyun.com Author Affiliations 1. Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China 2. Graduate School, Beijing University of Chinese Medicine, Beijing 100029, China Email: 1471911071@qq.com (Zongshi Qiu) liuxiaowei_1003@163.com (Xiaowei Liu) 1126873424@qq.com (Qin Yao) 746475225@qq.com (Yanbin Zhai) (p1)
Contact		
Contributions	3b	ZL and ZQ contributed to the conception of the study. The manuscript protocol was drafted by ZQ and revised by QY. The search strategy was developed by all the authors and will be performed by YZ and XL. YZ and XL will independently screen the potential studies, extract data from the included studies, assess the risk of bias, and complete the data synthesis. ZL will arbitrate in cases of disagreement and ensure the absence of errors. All authors approved the publication of the protocol (p9)
Amendments	4	If it is necessary to amend this protocol we will submit the data of each amendment, the description of change and rationale will be accompanied (p9)
Support		
Sources	5a	This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors (p9)
Sponsor	5b	None
Role of sponsor or funder	5c	None
Introduction		
Rationale	6	Sciatica is a common neuropathy characterized by pain radiating into the leg; it is usually caused by nerve root compression and irritation or inflammation of the sciatic nerve, and is often accompanied by lower back pain and neurological deficits in the lower limb. The pain is often associated with tingling, numbness, and weakness of the leg; it may be sudden in onset and then persist for days or weeks. Frymoyer reported that sciatica is very common, with a lifetime incidence varying from 13% to 40% and a corresponding annual incidence of sciatica episodes of 1-5%. Sciatica commonly affects people between the ages of 30 and 50 years, with the pain of sciatica significantly damaging health. Thus, according to the reporting of Youmei M. in Taiwan, sciatica has become a major cause of work absenteeism and a financial burden to society. Previous research has reported that 60% of patients with sciatica will have a mild disability and based on questionnaires at months 3 and 12 there is an 30% of patients that live with sciatica for more than 1 year, which results in an obvious decrease in quality of life. The current management of sciatica can be classified into pharmacological and non-pharmacological treatment. One reporting supports the effectiveness of nonopioid medication, epidural injections, and disc surgery. It also suggests that spinal manipulation, acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be considered. The use of pharmacological products such as anesthetics or corticosteroids has associated adverse effects including sedation, dizziness, ataxia, and nausea, and their effectiveness decreases with long-term use. Although according to the prior systematic review, epidural injections has better effect for pain reduction than nonopioids, related adverse effects to epidural injections have been reported. To date, there is no strong evidence-based medicine proving that non-pharmacological conservative treatment of Western medicine is effective; and surgical procedures are invasive, expensive, and may cause neurological complications. Currently, sciatica is one of the primary reasons for hospital consultations. Acupuncture has become a widely used method for treating sciatica in many countries, including China, the USA, and Japan. Acupuncture is reported to be effective in treating many types of musculoskeletal pain including lower back pain, fibromyalgia, osteoarthritis, and sciatica. However, the ability of acupuncture to successfully manage sciatica, either as a monotherapy or as an adjunct to Western medical care, remains unclear. This systematic review aims to assess the efficacy and safety of acupuncture for treating sciatica, with the resulting evaluation aiming to help clinicians make decisions on treating sciatica, and to help patients seeking further treatment options. (p2)
Objectives	7	The aim of this systematic review is to evaluate the effectiveness and safety of acupuncture in the management of sciatica for the patients. To this end, we will pose the two questions: What is the comparative efficacy and safety of acupuncture compared to sham acupuncture, anal care, or no treatment to reduce pain intensity in patients diagnosed with sciatica? Is there a definitive advantage of acupuncture compared with western medication? (p4)
Methods		
Eligibility criteria	8	Types of participants Patients with sciatica will be included, including those diagnosed with sciatica syndromes such as radiculopathy, nerve root compromise, nerve root compression, nerve root pain, and pain radiating below the knee. There will be no restriction on sex, age, or the intensity or duration of symptoms. Patients with acute infection, caudal equina syndrome, primary spinal stenosis, and lower back pain without sciatica will be excluded. Types of interventions Any type of invasive acupuncture will be included, such as acupuncture, electro-acupuncture, elongated needle acupuncture, three-edged needle acupuncture, fire needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and pyonex. Control interventions may include general care, sham acupuncture/placebo, and waiting list care. - Acupuncture versus other Western medicine treatment will be included. - Acupuncture plus another Western medicine treatment versus the same Western medicine treatment alone will be included. - RCTs comparing two different types of acupuncture will be excluded. - Acupuncture treatment without needle insertion (e.g., acupressure, laser acupuncture, and electrical stimulation) will be excluded. - Acupuncture combined with Chinese medicine, acupoint injection, and/or needle knife will be excluded. Types of outcome assessments Primary outcomes: - Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)). - Global assessment (the proportion of patients improved or cured). Secondary outcomes: - Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form health survey (SF-36) - Physical examinations. - Patient satisfaction. - Adverse effects (p1)
Information sources	9	A search strategy will be used and conducted according to the Cochrane handbook guidelines. The following nine databases will be searched from their inception to 30 October 2014: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Literature Database (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP database), Wan-Fang Database, China National Knowledge Infrastructure (CNKI), and Citation Information by National Institute of Informatics (CINI). The search strategy is based on the guidance of the Cochrane handbook. The key words include: "sciatica", "sciatic neuralgia", "disogenic sciatica", "disc herniation-induced sciatica", "bilateral sciatica", "acupuncture", "electro-acupuncture", "elongated needle", "three-edged needle", "fire needling", "auricular acupuncture", "abdominal acupuncture", and "pyonex" (p5)
Search strategy	10	This search strategy will also be applied to the other electronic databases. Search strategy used in PubMed database 1. randomized controlled trial pt 2. controlled clinical trial pt 3. randomized ti,ab 4. randomly ti,ab 5. groups ti,ab 6. trial ti,ab 7. or 1-6 8. acupuncture ti,ab 9. electro-acupuncture ti,ab 10. elongated needle ti,ab 11. three edged needle ti,ab 12. fire needle or warming needle ti,ab 13. auricular acupuncture ti,ab 14. abdominal acupuncture ti,ab 15. warm acupuncture ti,ab 16. pyonex ti,ab 17. or 8-16 18. sciatica ti,ab 19. sciatic neuralgia ti,ab 20. disogenic sciatica ti,ab 21. bilateral sciatica ti,ab 22. disc herniation-induced sciatica ti,ab 23. or 18-22 24. 7 and 17 and 23 (p12)
Study records:		
Data management	11a	All searched studies will be imported to EndNote software that can assist reviews to manage data and pick up duplicate publications, when two or more publications described a single trial, we included only one report. (p6)
Selection process	11b	Two authors (XL and YZ) will screen the title and abstracts of all the articles to confirm that they contain eligible trials, with the full text to be reviewed if necessary. Any disagreement during the selection of studies will be discussed and decided by a third author (ZL). Details of the selection process are shown in the PRISMA flow chart (Figure 1) (p6)
Data collection process	11c	A data extraction form will be used to collect data. A small scope trial will be done before the systematic review is conducted to confirm that there is no obvious divergence between those collecting data. Two authors (XL and YZ) will independently extract the data and take the following aspects into consideration: general information (name and year of publication, date of extraction, title of study, and author's publication details), study characteristics, eligibility criteria, interventions, outcome measurements, duration, adverse events, results, and the type of needle used. These data will then be entered into RevMan 5.3.3 software for analysis. Any disagreement will be discussed and finally decided upon by a third author (ZL). (p6)
Data items	12	We will extract the information of each study, including the type of control used, frequency and duration of treatment, patient characteristics (age, gender, duration of symptoms, type of sciatica), trial design, trial size, duration of follow-up, type and source of financial support, if appropriate. (p6)
Outcomes and prioritization	13	Primary outcomes: - Pain intensity. Any validated measurement scales will be included (e.g., visual analog scale (VAS), numeric rating scale (NRS), short-form McGill Pain Questionnaire (SF-MPQ)). - Global assessment (the proportion of patients improved or cured). Secondary outcomes: - Quality of life, e.g., as assessed using the Medical Outcomes Study 36-item Short Form health survey (SF-36) - Physical examinations. - Patient satisfaction. - Adverse effects (p5)
Risk of bias in individual studies	14	The risk of bias assessment will be based on the Cochrane Collaboration Risk of Bias Tool. Two authors (QY and YZ) will independently evaluate methodological quality using the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Other sources of bias may be caused by the different types of needles used, the duration of sciatica, the length of therapy, and the age of patients. Taking these domains into account, each trial will be categorized into low risk, high risk, and unclear risk. Any disagreements will be discussed and resolved by a third author (ZL). (p6-7)
Data synthesis	15a	If meta-analysis can be conducted, RevMan 5.3.3 software will be used to combine the RR with 95% CIs for dichotomous outcomes and the weighted mean difference or standardized mean difference with 95% CIs for continuous data. If the result of the test for heterogeneity results in $p > 0.1$, the fixed-effect model will be used to combine the data; if $p < 0.1$, the random effect model will be used. (p8)
	15b	Analysis will be based on available data of included studies. For dichotomous data, the risk ratio (RR) will be calculated with 95% confidence intervals (CIs). For continuous variables, means and standard deviations will be used to calculate a mean difference with a 95% CI. (p8)
	15c	The following subgroup analyses will be conducted to assess the heterogeneity of the studies: Clinical considerations - Acupuncture versus sham acupuncture - Types of sciatica (non-disogenic sciatica versus disogenic sciatica) Methodological considerations - Trials with unclear or high risk of bias (p8)
	15d	If the data will not be suitable for combining quantitatively, in the condition, a systematic narrative synthesis will be provided with the information that presented in the text to summarise and explain the characteristics and findings of the included studies. (p8)
Meta-bias	16	Funnel plot will be used to assess the reporting biases if 10 or more trials are included in a meta-analysis. (p7)
Confidence in cumulative estimate	17	Details of acupuncture and control interventions were extracted on the basis of the revised Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA), a checklist that intended for use in conjunction with CONSORT and can estimate randomized controlled trials of acupuncture, include acupuncture rationale, needling details, treatment regimen, co-intervention, control interventions, treating background. (p7)