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Effectiveness of Acupuncture for Low Back Pain

A Systematic Review

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Study Design. A systematic review of randomized controlled trials (RCTs).

Objective. To explore the evidence for the effectiveness of acupuncture for nonspecific low back pain (LBP).

Summary of Background Data. Since the most recent systematic reviews on RCTs on acupuncture for LBP, 6 RCTs have been published, which may impact on the previous conclusions.

Methods. Searches were completed for RCTs on all types of acupuncture for patients with nonspecific LBP published in English. Methodologic quality was scored using the Van Tulder scale. Trials were deemed to be high quality if they scored more than 6/11 on the Van Tulder scale, carried out appropriate statistical analysis, with at least 40 patients per group, and did not exceed 20% and 30% dropouts at short/intermediate and long-term follow-up, respectively. High quality trials were given more weight when conducting the best evidence synthesis. Studies were grouped according to the control interventions, *i.e.*, no treatment, sham intervention, conventional therapy, acupuncture in addition to conventional therapy. Treatment effect size and clinical significance were also determined. The adequacy of acupuncture treatment was judged by comparison of recommendations made in textbooks, surveys, and reviews.

Results. Twenty-three trials (n = 6359) were included and classified into 5 types of comparisons, 6 of which were of high quality. There is moderate evidence that acupuncture is more effective than no treatment, and strong evidence of no significant difference between acupuncture and sham acupuncture, for short-term pain relief. There is strong evidence that acupuncture can be a useful supplement to other forms of conventional therapy for nonspecific LBP, but the effectiveness of acupuncture compared with other forms of conventional therapies still requires further investigation.

Conclusion. Acupuncture *versus* no treatment, and as an adjunct to conventional care, should be advocated in the European Guidelines for the treatment of chronic LBP.

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Low back pain (LBP) has a high lifetime prevalence in which nonspecific LBP represents a large majority of cases.[1,2] Although 90% of patients have improved at 1 month,[3] the majority continue to be symptomatic at 1 year, with only 21% to 25% completely recovered in terms of pain and disability.[4,5] Overall, LBP is one of the most costly conditions in the UK, which is in line with findings in other countries, leading to a total cost of £10,668 million (including direct health care cost and indirect cost *e.g.*, informal care, production losses related to LBP).[5] Furthermore, costs caused by recurrence of LBP contribute substantially more, than costs in first episodes, to the total burden of LBP.[6]

The Royal College of General Practitioners (RCGP) recommends that LBP should shift from secondary to primary care, and the aim should be a rapid return to normal function.[7] There is much current debate on how to achieve this return to normal function. Among complementary and alternative medicine (CAM), acupuncture has been demonstrated as a powerful therapy, which is associated with clinically relevant improvements for LBP and is receiving increasing recognition from both the public and professionals.[8,9] Two recent randomized controlled trials (RCTs) evaluating economics, 1 in the UK and the other in Germany, shows that acupuncture is relatively cost effective in terms of quality of life for LBP.[10,11] These endorsements seem to have translated into practice in that a growing number of GP practices in England are providing access to acupuncture for their patients.[12,13] Moreover, the public are increasing their interest in the use of acupuncture, *e.g.*, a recent survey in the United States indicated that most LBP patients would be "very likely" to try acupuncture if they did not have to pay out of pocket, and their physician thought it was a reasonable treatment option.[14]

Since the most recent systematic reviews on RCTs on acupuncture for LBP,[15,16] 6 RCTs (4 with large sample sizes) have been published,[11,15–21] which may impact on the conclusions drawn by the previous reviews. Therefore the aim of this review was to investigate the updated evidence on the effectiveness of acupuncture for nonspecific LBP using rigorous rating criteria.

■ Materials and Methods

Study Identification

RCTs in English were searched in Medline (1966–2008), Pubmed (1950–2008), EMBASE (1974–2008), AMED (1985–2008), ProQuest (1986–2008), CINAHL (1982–2008), ISI Web of Science (1981–2008), and Cochrane Controlled Trials Register (1980–2008). Medical Subject Heading (MeSH) words including acupuncture/electroacupuncture and low back pain/back pain/lumbar vertebrae/lumbosacral region/sprains and strain and randomized controlled trials/controlled clinical trials were used. References in relevant reviews and RCTs, and 4 key journals, Complementary Therapies in Medicine (2000–2007), Spine (1996–2008), Anesthesia (1998–2008), and Clinical Acupuncture and Oriental Medicine (1999–2007), were manually searched.

Study Selection

Two reviewers independently identified potentially eligible trials. Studies included were RCTs of all types of acupuncture with adequate treatment, compared with different types of control interventions for adults (≥18 years) with nonspecific LBP, using at least 1 of the following outcome measures that are considered to be the most important for LBP (pain, functional disability, general health status, physiologic outcomes, a global measure of improvement, return to work) and published in English. RCTs comparing different forms of acupuncture or on specific LBP conditions (*e.g.*, pregnancy) were excluded. Nonspecific LBP was defined as pain below the 12th costal margin and above the inferior gluteal folds, with or without radiating leg pain, for which specific etiologies such as infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome or cauda equina syndrome, and other relevant pathologic entities had been excluded.[22]

Treatment Comparisons

The included studies were grouped according to the control groups, *i.e.*, no treatment, sham interventions, conventional therapy, acupuncture or sham acupuncture in addition to conventional therapy.

Assessment of Acupuncture Treatment Adequacy

Data on intervention details were extracted according to the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.[23] The adequacy of acupuncture treatment was judged by comparing the parameters in RCTs to those from textbooks, surveys, and review sources. Trials with inadequate treatment procedures were excluded from this review.

Assessment of Methodologic Quality

Data were extracted and independently scored by 2 reviewers using the Van Tulder scale,[24] which has been adopted by the European guidelines for LBP[22] to assess the methodologic quality of trials. If there was any disagreement, a third reviewer would be consulted to come to a consensus. In this review, a high-quality study should score 6 or more on the Van Tulder scale, carry out a between-group statistical comparison, have at least 40 patients per group (to enable adequate power),[25] have a dropout rate less than 20% for short-term (<3 months) and intermediate term (≥3 months and <1 year) follow-up, and 30% for long-term (≥1 year) follow-up.[24,26,27] Although dropout rates have been included in Van Tulder scale, in this review, they were considered independently for each study because of their significant impact on the study results. More weight was given to high quality studies, when conducting the best-evidence synthesis on the effectiveness of acupuncture for nonspecific LBP.

Data Analysis

Best Evidence Synthesis. Best evidence synthesis was performed by attributing various levels of evidence to the effectiveness of acupuncture for nonspecific LBP, based on the methodologic quality and the results of the original RCTs[24,26]:

Level 1: strong evidence–consistent findings among multiple high-quality RCTs (when >75% of the RCTs report the same findings).

Level 2: moderate evidence–consistent findings among multiple low-quality RCTs and/or 1 high-quality RCT.

Level 3: limited evidence–1 low-quality RCT.

Level 4: conflicting evidence–inconsistent findings among multiple RCTs.

Level 5: no evidence: no RCTs.

The results of the original RCTs were based on the between-group statistical significant difference ($P < 0.05$), or on the author's conclusions when *P*-values were not available, for 2 primary outcomes, pain and functional disability.

Effect Size. Review Manager 4.2.7 was used for statistical analysis. Means and standard deviations (SD) for pain and functional disability were extracted, and if possible, the treatment effect size of each RCT was plotted as point estimates *i.e.*, standardized mean difference (SMD) for continuous outcomes and odds ratio (OR) for dichotomous outcomes in a random-effect model, each with corresponding 95% confidence intervals (95% CI) and 2-tailed *P*-values. The formula is shown below:

SMD = (Mean in the acupuncture group − Mean in the control group)/Pooled SD of both groups

OR = The ratio of successes to failures in the acupuncture group/The ratio of successes to failures in the control group

The effect size was defined as 0.20 for small, 0.50 for medium, and 0.80 for large effects.[28] For cross-over trials, the summary data were used as if they had been derived from parallel trials. In this review, the effect sizes were grouped according to the control interventions and follow-up time point.

Clinical Significance. In order to identify whether the changes observed with acupuncture were clinically significant compared to other forms of treatment, mean differences in pain and functional disability were calculated (acupuncture mean change over time minus control mean change over time), which were then compared to a minimal clinically important difference (MCID). MCID was defined as the cut-off point that best discriminated between improvement and nonimprovement in clinical practice for individuals. Considering the overall effect of acupuncture (specific and nonspecific), the MCID in this review was set at 2 points (0–10 scale) or 20 points (0–100 scale) for pain reduction (*i.e.*, −20% of the total score).[29–32] The MCID for functional disability was also set, *e.g.*, 30% reduction of score from baseline on Roland-Morris Disability Questionnaire (RMDQ) (24 items).[33,34] Clinical significance was deemed to be clearly achieved when both limits of 95% CI of mean difference was greater than the MCID.

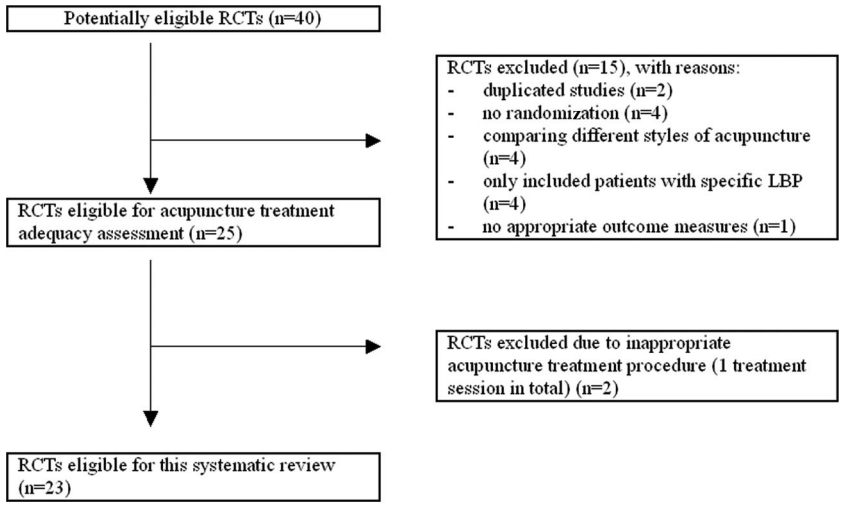

Figure 1. The QUORUM statement flow diagram.

■ Results

Study Selection

In total, 1606 studies were found, and 40 potentially eligible RCTs were identified, 15 of which were excluded in the first step (Figure 1).

Adequacy of Acupuncture Treatment

Data on acupuncture treatment details were extracted and summarized. In general, acupuncture treatment details, *i.e.*, chosen points, number of points needled, needle sensation, needle retention time, treatment frequency, and treatment sessions, were generally in line with textbooks,[35–39] surveys,[40–42] and reviews.[43–48] The exception is that 2 RCTs provided only 1 treatment session in total for chronic LBP, which was considered inadequate and excluded from this review.[49,50]

Finally, 23 RCTs were included, and the process of study selection was shown by a flow diagram as recommended in the Quality of Reporting of Meta-Analysis (QUOROM) statement[51] (Figure 1).

Varied styles of acupuncture have been used in the included RCTs, *i.e.*, individualized (52%), standardized (22%), and semistandardized (26%) acupuncture. Semistandardized acupuncture has been defined as a set formula of points, supplemented by some additional points individually chosen for each patient.

Study Characteristics

Twenty-three RCTs representing 6359 LBP patients were included, and their study characteristics are provided in Table 1. The sample size ranged from 17 to 3093, where 9 studies (39%) included between 50 and 100 subjects and 10 studies (43%) included more than 100 subjects. Nineteen (83%) studies were on chronic LBP (≥12 weeks), 1 study on subacute LBP (≥4weeks and <12weeks), and 3 studies on chronic and subacute LBP.

All 23 studies measured pain intensity, using visual analogue scales (VAS), numerical rating scales (NRS), SF-36 bodily pain dimension, Von Korff chronic pain grading scale, or LBP rating scale. Sixteen (70%) studies measured functional disability. Furthermore, 9 studies (39%) measured range of motion (ROM), 11 (48%) measured analgesic intake, 8 (35%) measured general health status, and some included the measures such as global assessment (2 RCTs) and adverse effects (5 RCTs).

Eight studies (35%) only had short-term follow-up, 12 (52%) intermediate term, and only 3 (13%) long-term follow-up. Thirteen studies (57%) had dropout rates less than 20% and 30% for short-/intermediate and long-term follow-up, respectively. Fourteen studies used follow-up interview 43% of them with large dropouts, and 9 studies used telephone/mail follow-up with 22% of them with large dropouts, which seemed superior over interview.

Thirteen studies did not account for missing data, whereas 10 studies (43%) adopted intention-to-treat analysis (ITT), of which 2 studies had no dropout,[17,52] 4 carried baseline,[53] discharge,[18] or last values forward,[11,54] 2 counted the missing data as failures/successes,[21,55] and 2 studies did not specify their ITT methodology.[56,57] However, no relationship could be explored between the analytic methods and the results.

Methodologic Quality Assessment

In summary, although 16/23 of the studies (70%) scored highly on the Van Tulder scale, only 8/23 had more than 40 patients per group of which 2 studies had high dropouts,[55,58] leaving only 6/23 high quality studies.[11,18,20,21,56,59]

Best Evidence Synthesis

In total 5 types of comparisons were made as below.

Acupuncture *Versus* No Treatment (n = 3). One high[18] and 2 low quality studies[60,61] provided moderate evidence that acupuncture was more effective than no treatment for short-term pain relief and conflicting evidence for intermediate pain relief.[60] There was moderate evidence for such a comparison for short-term functional improvement[18] (Tables 1, 2).

Table 1. Characteristics of 23 Included RCTs (1966–2008)

Study	Blind	Intervention	Sample Size/Dropout Rate	Participant: Age (yr)	Participant: Time Injury	Participant: Grade	Participant: Key Inclusion Criteria	Outcome Measures/ Follow-up Time/Methods	Analysis/Author Conclusions/Flaws
Haake 2007	Patient assessor	MA Sham AT (superficial at non AT points) CT (German guideline-based, PT, exercise etc.)	N = 1162 387/4% (6 wk, 3 mo) 3% (6 mo) 387/3% (6 wk, 3–6 mo) 387/7% (6 wk, 3 mo) 6% (6 mo)	>18 yr	≥6 mo	CPGS grade 1, HFAQ <70%,	Nonspecific LBP, no previous AT Rx for cLBP, therapy free >7 day	*Von Korff CPGS (0–10), HFAQ SF12, patient global assessment (1–6), medication use, AT Rx, adverse events, patient blinding time: baseline, 1.5, 3, 6 mo method: telephone	ITT: sensitivity analysis using best and worst imputation data Author (+) SS favoring AT and Sham AT (*vs.* CT) but no SS between AT *vs.* Sham AT, on pain for cLBP at 6 mo
Brinkhaus 2006	Patient	MA Sham AT (superficial at non-AT points) No Rx	N = 298 146/4% (8 wk), 5% (26 wk), 6% (52 wk) 73/4% (8 wk), 4% (26 wk), 7%(52 wk) 79/6% (8 wk)	40–75	≥6 mo	VAS ≥40	Nonspecific LBP, only use of oral NSAIDs 4 wk before Rx	*Pain (VAS 0–100 mm) Pain disability index, SF-36, emotional aspect of pain, depression, time with limited function/pain/ analgesics intake Time: baseline, 8, 26, 52 wk Method: mail	ITT: sensitivity analysis with missing values replaced Author (+) SS favoring AT and Sham AT (*vs.* No Rx) but no SS between AT *vs.* Sham AT, on pain for cLBP
Itoh 2006	Patient assessor	Cross-over after 3 wk washout period Trigger point AT Sham AT (nonpenetrating)	N = 26 13/8% (end of phase1) 23% (end of phase 2) 13/15% (end of phase 1) 31% (end of phase 2)	≥65 yr	≥6 mo	N/A	Nonspecific LBP, without other conflicting/on-going Rx	*VAS (0–100), *RMDQ (0–24) Blinding Time: VAS-baseline, 1, 2, 3, 6, 7, 8, 9, 12 wk post-Rx; RMDQ-baseline, 3, 6, 9, 12 wk post-Rx Methods: interview	No ITT Author (+) SS favoring trigger point AT (*vs.* Sham AT) on pain and function for cLBP at short-term for elderly patients; however, such SS was not maintained after cross-over Rx. Flaws: very small sample size, large dropouts at end of phase 2
Thomas 2006	No	TCM MA + CT CT (PT, medication, back exercise etc)	N = 241 160/8% (3 mo), 7% (12 mo), 23% (24 mo) 80/8% (3 mo), 15% (12 mo), 27% (24 mo)	18–65	4–52 wk	N/A	Nonspecific LBP	*SF36 bodily pain (0–100), *EuroQoL, *preference-based single index MPQ, ODQ, SF-36, medication, pain-free mo, worry on LBP, patient satisfaction, safety and acceptability of AT Time: baseline, 3, 12, 24 mo Method: mail, home visit, telephone	ITT: sensitivity analysis with missing values replaced by last value carried forward Author (+) AT was safe and acceptable to nonspecific LBP patients SS favoring MA + CT (*vs.* CT) in pain with small benefit at 24 mo
Witt 2006	Assessor	MA + CT CT	N = 3093 1549/13% (3 mo) 1544/19% (3 mo)	≥18 yr	>6 mo	N/A	Nonspecific LBP	*HFAQ (0–100), pain, LBP rating scale, SF36, analgesics, adverse effects Time: baseline, 3 mo Method: mail	ITT: sensitivity analysis with missing values replaced by last value carried forward Author (+) SS favoring AT + CT (*vs.* CT) on back pain, function and cost-effectiveness for cLBP at 3 mo
Tsui 2004	Patient	EA + back exercise Heat EA + back exercise Back exercise	N = 42 14/0% (all follow-up) 14/0% (all follow-up) 14/0% (all follow-up)	20–55	≥3 mo	N/A	Mechanical LBP radiated down to the thigh/calf, SLR (+)	*Pain: NRS (1–10), *function: RMDQ *ROM: SLR time: baseline, 2, 4 wk, 1mo Method: during Rx visit	ITT (no drop out) Author (+) SS favoring EA (*vs.* control) on NRS, SLR after 8 Rx and at 1mo Flaws: small sample size

(*Continued*)

Table 1. Continued

Study	Blind	Intervention	Sample Size/Dropout Rate	Participant				Outcome Measures/ Follow-up Time/Methods	Analysis/Author Conclusions/Flaws
				Age (yr)	Time Injury	Grade	Key Inclusion Criteria		
Yeung 2003	Assessor	EA + back exercise Back exercise	N = 52 26/0% (discharge, 1 mo), 4% (3 mo) 26/0% (discharge) 8% (1mo, 3 mo)	18–75	≥6 mo	N/A	Nonspecific LBP, not receiving AT in 6 mo, not receiving PT in 3 mo	*Pain: NRS (0–10), *Disability: Aberdeen LBP scale, lumbar spinal ROM, trunk strength Time: baseline, discharge, 1 mo, 3 mo Method: telephone or mail	ITT: carried the baseline value forward Author (+) EA + back exercise might be an effective option for pain and disability of cLBP
Meng 2003	No	EA + CT CT (NSAIDs, muscle relaxant, paracetamol, back exercises)	N = 55 31/10% (baseline) 23% (follow-up) 24/4% (baseline)	≥60	≥12 wk	N/A	Nonspecific LBP, imaging study of spine, no previous AT for LBP, no use of corticosteroids, muscle relaxants etc. in 3 mo	*Function: modified RMDQ (0, 2, 6, 9 wk) Pain: VAS (0, 2, 6, 9 wk) Prior knowledge and expectations of AT Patient impressions of AT after Rx No. tablets intake in a diary Adverse events Time: baseline, 0, 2, 6, 9 wk (Rx = 5 wk) Method: N/A	ITT: carried the last value forward Author (+) AT is an effective, safe adjunctive Rx for cLBP in older patients.
Giles 2003	No	MA NSAIDs (celebrex, vioxx, paracetamol for 9 wk) Chiropractic spinal manipulation	N = 115 36/44% (discharge) 43/56% (discharge) 36/33% (discharge)	≥17	≥13 wk	N/A	Uncomplicated (*i.e.*, mechanical) spinal pain	*Pain: VAS *Function: ODQ General health: SF36, *ROM Pain frequency, SLR angle Time: baseline, during-Rx, discharge Method: interview	No adequate ITT: ITT after randomization, before Rx Author (−) Manipulation, if not contraindicated, has greater short-term improvement than AT. However, the data do not strongly support use of only manipulation/ AT/NSAIDs Flaws: no BGSC; large dropouts
Kerr 2003	Patient Assessor	MA Placebo TENS	N = 60 30/13% (on-Rx) 17% (6 mo) 30/33% (on-Rx) 57% (6 mo)	≥18	>6 mo	N/A	Nonspecific LBP, no contraindications to AT	*SF36, ROM *Pain: MPQ, VAS Time: baseline, discharge, 6mo Method: mail	No ITT Author (N) Improvement over time in both groups. Flaws: Large dropouts.
Molsberger 2002	Patient	MA + CT (daily PT, physical exercise, back school, mud packs, infrared heat therapy) Sham MA + CT CT	N = 186 65/11% (on-Rx) 28% (3 mo) 60/3% (on-Rx) 40% (3 mo) 61/5% (on-Rx) 33% (3 mo)	20–60	≥6 wk,	VAS ≥ 50 mm	Nonspecific LBP, communicate in German, no previous AT, not on analgesics, no incapacity for work >6mo, no pending compensation claims	*Pain: VAS (3 mo) Pain: VAS (post-Rx), Rx efficacy: (discharge, 3mo), finger-to-ground distance (post-Rx) Daily pain diary on VAS Time: baseline, discharge (Rx = 4 wk), 3 mo Method: interview	ITT: counted missing data as failures/successes/ failures if missing in AT group and successes if missing in control group, respectively MA + CT: sham MA + CT Author (+) Flaws: large dropouts (3 mo) MA + CT: CT Author (+) AT can be an important supplement of CT for cLBP. Flaws: large dropouts (3 mo)

(*Continued*)

Table 1. Continued

Study	Blind	Intervention	Sample Size/Dropout Rate	Participant				Outcome Measures/ Follow-up Time/Methods	Analysis/Author Conclusions/Flaws
				Age (yr)	Time Injury	Grade	Key Inclusion Criteria		
Leibing 2002	Patient assessor	AT (body-AT + ear-AT) + PT (standardized) No Rx + PT Sham AT + PT	N = 150/(baseline) N = 131/(on-Rx) 40/13% (discharge) 18% (9 mo) 46/15% (discharge) 35% (9 mo) 45/11% (discharge) 31% (9 mo)	18–65	>6 mo	N/A	Nonspecific, nonradiating LBP	*Pain: VAS (0–10 cm), *pain disability Psychological distress Fingertip-to-floor distance Time: baseline, discharge, 9 mo Method: interview	No adequate ITT: ITT after randomization, before Rx. AT + PT: No Rx + PT Author (+) AT + PT: sham AT + PT Author (N) A significant improvement by traditional AT *vs.* PT but not *vs.* sham-AT for cLBP There was placebo effect of TCM AT
Tsukayama 2002	Assessor	EA + PTN (press tack needles) TENS	N = 20 10/10% (on-Rx) 10/0% (discharge)	>20	≥2 wk	N/A	Nonspecific LBP	*Pain: VAS Japanese Orthopaedic Association score Adverse events Time: baseline, discharge Method: interview	No ITT Author (+) EA appeared more useful than TENS in the short-term effect on LBP. Flaws: very small sample size
Carlsson 2001	Patient assessor	MA EA (after 2–3 sessions of MA) Placebo TENS	N = 51 (on-Rx) N = 50 (analyzed) 34/32% (3 mo) 38% (6 mo) 16/44% (3 mo) 63% (6 mo)	N/A	≥6 mo	N/A	Nonspecific LBP, no previous AT Rx.	*Global pain: pre-Rx, 1, 3, ≥6 mo Pain diaries Pain: VAS (twice daily), analgesic intake, quality of sleep, activity level Time: baseline, discharge, 1, 3, 6 mo or longer Method: interview	No ITT Author (+) a long-term pain-relieving effect of AT *vs.* placebo in some patients with cLBP. Flaws: large dropouts at 3 and 6mo
Cherkin 2001	Assessor	EA/MA Massage Self-care education	N = 262 94/5% (10 wk) 4% (52 wk) 78/1% (10 wk) 3% (52 wk) 90/8% (10 wk), 8% (52 wk)	20–70	Persistent	≥4 (0–10 scale)	Persistent nonspecific LBP, no AT/massage for LBP within the past year	*Symptoms, *function: RMDQ, Disability, cost, and use of medications, satisfaction, SF-12 Physical and Mental Health scales, no. days of aerobic and back exercise Time: baseline, 4, 10, 52 wk (1 yr) Method: computer-assisted telephone	ITT: method N/A AT: massage Author (−) TCM AT was relatively ineffective AT: self-care education Author (N) No SS between AT and self-care education for LBP in short/long-term follow-up
Grant 1999	Assessor	MA TENS	N = 60 32/6% (on-Rx) 28/4% (on-Rx) 7% (3 mo)	≥60	≥6 mo	N/A	LBP, no previous Rx of AT/TENS	*Pain: VAS, *pain scale on Nottingham Health Profile,* analgesic intake *Spinal flexion from C7 to S1. Time: baseline, discharge, 4 days, 3 mo Method: interview	No ITT Author (N) AT and TENS had demonstrable benefits, which outlasted the Rx period, and AT may improve spinal flexion. Flaws: no BGSC
Giles 1999	No	MA, ±EA (low voltage) Chiropractic spinal manipulation NSAIDs	N = 77 20/10% (on-Rx) 36/11% (on-Rx) 21/10% (on-Rx)	≥18 yrs	≥13 wk	N/A	Chronic nonspecific spinal pain, without contraindication to manipulation/ medication	*Disability: ODI *Pain: VAS *Pain frequency, *% of patients changed to other Rx Time: baseline, discharge (Rx = 4 wk) Method: interview	No ITT AT: spinal manipulation Author (−) Spinal manipulation, has greater improvement than AT and medicine Flaws: no BGSC AT: NSAIDs Author(U) flaws: no BGSC

(*Continued*)

Table 1. Continued

Study	Blind	Intervention	Sample Size/Dropout Rate	Participant: Age (yr)	Participant: Time Injury	Participant: Grade	Participant: Key Inclusion Criteria	Outcome Measures/ Follow-up Time/Methods	Analysis/Author Conclusions/Flaws
Thomas and Lundberg 1994	No	MA EA (low frequency) EA (high frequency) No Rx	N = 43 33/10% (on-Rx) 18% (6 mo) 10/0% (6 mo)	N/A	≥6 mo	Varied	Nonspecific LBP with muscle spasm, affected by postural changes, restricted ADL and trunk/hip movement	*ADL: VAS *Verbal descriptors of pain *Subjective assessment *Mobility: ROM, SLR Time: baseline, discharge, 6 mo Method: interview	No ITT author (+) After 6 wk, patients with Rx showed SS improvement on 3/4 measures *vs.* no Rx After 6 mo, patients with 2 Hz EA showed SS improvement *vs.* no Rx
Lehmann 1986	No	EA TENS (over center of pain/related nerve trunk) Placebo: mock TENS	N = 53 17/24% (on-Rx) 29% (6 mo) 18/22% (on-Rx) 22% (6 mo) 18/17% (on-Rx) 0% (6 mo)	N/A	≥3 mo	N/A	Nonspecific LBP, patients with at least minimal levels of motivation and the level of disability would warrant the expense of inpatient Rx	*Low Back Rating Scale Score Patient: trunk strength, spine ROM, pain (VAS), disability, ADL Physician: pain, impairment, medication *Peak pain: VAS, *total rating scale score: education, exercise etc Time: baseline, discharge, 6 mo Method: interview	ITT: method N/A Author (N) No SS between Rx groups on overall rehabilitation. All 3 Rx groups ranked the contribution of education greater than EA. However, EA group showed greater improvement than the others · AT group had less pain on VAS Flaws: No BGSC; Very small sample size; Large dropouts post-Rx
MacDonald 1983	Assessor	Superficial MA EA Placebo TENS	N = 17 8/0% 9/0%	N/A	≥1 yr	N/A	17 patients with cLBP who failed to derive sufficient relief from CT, warranted referral to a pain clinic.	*Pain: VAS, *pain produced by activities, p*ain relief score, *patient's mood, *physical signs, *severity of pain numerically Time: baseline, discharge Method: interview	ITT: No missing data Author (+) AT achieved better responses than placebo, with 4 of the 5 inter-group differences were SS. An overall mean for all 5 measures showed SS of AT *vs.* placebo Flaws: very small sample size
Mendelson 1983	Patient assessor cross-over	MA Placebo (lidocaine inj. at non-AT, nontender sites)	N = 190 95/19% (on-Rx) 95/19% (on-Rx)	N/A	chronic	N/A	LBP	*VAS: 3 times/wk, *MPQ *Changes in pain and disability *Analgesic intake Time: baseline, during-Rx, post-each-Rx Method: interview	No ITT Author (N) Overall reduction in pain score was 26% for AT and 22% for placebo, the difference was not SS
Coan 1980	No	MA/EA No Rx	N=50 25/8% (on-Rx) 8% (40wk) 25/36% (on-Rx) 36% (40wk)	N/A	≥6 mo		LBP, no previous AT Rx, ≤2 back surgeries.	*Mean hrs of pain per day, *NRS scale, *pain pills intake per wk *Mean limitation of activity Time: AT/Control: at enrolment, discharge, 40 wk Method: mail	No ITT Author (+) AT was a superior form of Rx for LBP Flaws: no BGSC; large dropouts
Gunn 1980	No	Muscle motor band MA/EA + CT (PT, remedial exercises) CT	N = 56 29/3% (on-Rx) 0% (final follow- up) 27/7% (on-Rx) 0% (final follow- up)	20–62	≥12 wk	N/A	Male patients with LBP, despite all traditional medical or surgical therapy	*Pain and work status Time: discharge, 12, 27.3 wk Method: telephone/ mail, reports, Workers Compensation Board staff	No ITT Author (+) AT was clearly and significantly better than CT for LBP ($P > 0.005$).

*Primary outcomes.
AT indicates acupuncture; EA, electroacupuncture; MA, manual acupuncture; TCM, traditional Chinese medicine; LBP, low back pain; cLBP, chronic low back pain; Rx, treatment; CT, conventional therapy (any other therapy except AT); CPGS, Von Korff Chronic Pain Grade Score; HFAQ, Hanover Functional Ability Questionnaire; OT, occupational therapy; PT, physiotherapy; NSAIDs, non-steroidal anti-inflammatory drugs; TENS, transcutaneous electrical nerve stimulation; N/A, not available; SS, statistically significant; Q, questionnaire; BGSC, between-group statistical comparison; NRS, numerical rating scale; VAS, visual analogue scale; MPQ, McGill pain questionnaire; ROM, range of motion; SLR, straight leg raise; ODQ, Oswestry disability index; RMDQ, Roland-Morris disability questionnaire; SF36, 36 quality-of-life questionnaire; ADL, activity of daily life; +, positive conclusion; −, negative conclusion; N, neutral conclusion; U, unclear conclusion.

Table 2. Van Tulder Score of Included 23 RCTs (1966–2008)

Author	Year	A	B	C	D	E	F	G	H	I	J	K	Score
Haake	2007	+	+	+	+	−	+	+	+	+	+	+	10
Brinkhaus	2006	+	+	+	+	−	+	?	+	+	+	+	9
Itoh	2006	+	?	+	+	−	+	+	?	−	+	−	6
Thomas	2005	+	+	+	−	−	−	+	+	+	+	+	8
Witt	2006	+	?	+	−	−	+	+	+	+	+	+	8
Tsui	2004	?	?	+	−	−	+	+	+	+	+	+	7
Yeung	2003	?	+	+	−	−	+	+	+	+	+	+	8
Meng	2003	+	+	+	−	−	−	−	+	−	+	+	6
Giles	2003	+	+	+	−	−	−	?	+	−	+	−	5
Kerr	2003	+	+	+	+	−	+	+	+	−	+	−	8
Molsberger	2002	+	+	+	+	−	−	+	+	−	+	+	8
Leibing	2002	+	+	+	+	−	+	?	+	−	+	−	7
Tsukayama	2002	+	+	+	−	−	+	+	+	+	+	−	8
Carlsson	2001	+	+	+	+	−	+	?	+	−	−	−	6
Cherkin	2001	+	+	+	−	−	+	+	+	+	+	+	9
Grant	1999	?	+	−	−	−	+	?	+	+	+	−	5
Giles	1999	+	+	+	−	−	−	?	+	+	+	−	6
Thomas	1994	−	?	+	−	−	?	−	+	+	+	−	4
Lehmann	1986	?	?	?	−	−	−	+	+	−	+	+	4
MacDonald	1983	?	?	+	−	−	+	−	+	+	?	+	5
Mendelson	1983	+	?	−	+	−	+	−	+	+	+	−	6
Coan	1980	+	+	−	−	−	−	−	−	−	−	−	2
Gunn	1980	+	−	+	−	−	−	−	+	+	+	−	5
Total		17	15	19	8	0	14	11	21	14	20	11	Mean=6.5

Was the method of randomization adequate? Was the treatment allocation concealed? Were the groups similar at baseline regarding the most important prognostic indicators? Was the patient blinded to the intervention? Was the care provider blinded to the intervention? Was the outcome assessor blinded to the intervention? Were cointerventions avoided or similar? Was the compliance acceptable in all groups? Was the dropout rate described and acceptable? Was the timing of the outcome assessment in all groups similar? Did the analysis include an intention-to-treat analysis?
+ indicates yes; −, no; ?, don't know.

Acupuncture *Versus* Sham Interventions (n = 8)

1. Acupuncture *versus* sham acupuncture (n = 4): 3 high-quality studies provided strong evidence of no significant difference between acupuncture and sham acupuncture, for short-term and intermediate pain relief and functional improvement (n = 298 and n = 1162, respectively, using superficial needle insertion at nonacupoints without stimulation as sham acupuncture),[18,21] or for pain relief during and at the end of treatment (n = 190, crossover design using superficial needle insertion with 2% lidocaine injection as sham acupuncture).[59] Although 1 low-quality study showed trigger point acupuncture was significantly superior over sham acupuncture (nonpenetrating) for pain and functional improvement at short-term follow-up, such a conclusion was unreliable given its small sample size (n = 26).[19]
2. Acupuncture *versus* placebo transcutaneous electrical nerve stimulation (TENS) (n = 4): two low-quality studies showed no significant difference for pain relief between acupuncture and placebo TENS at discharge[57,62] and intermediate follow-up.[57] However, the conclusion is unreliable because both of them included less than 40 patients per group and had large dropouts. The study by Lehmann et al[57] also lacked between-group statistical comparisons. In contrast, the other 2 low-quality studies showed significant superior effects of acupuncture over placebo TENS for short/intermediate term pain relief.[52,63] However, their results were also unreliable because 1 study had high dropouts and both had less than 40 patients per group[63] (Tables 1, 2).

Acupuncture *Versus* Conventional Therapy (n = 6). In this review, conventional therapy was defined as any other therapy except acupuncture, *e.g.*, standard GP care including medication, physiotherapy (PT) *etc.* As a result, 6 studies provided conflicting evidence.

Acupuncture was significantly superior, over conventional therapy for pain and functional improvement at short/intermediate term follow-up in 1 high-quality study,[21] or over TENS for pain relief at discharge in 1 low-quality study, which was, however, unreliable due to the very small sample size (n = 20).[64] Two low-quality studies found no significant difference between acupuncture and TENS,[57,65] which was also unreliable due to the small sample size and lack of between-group statistical comparisons in both studies, and high dropouts.[57]

One high-quality RCT (n = 262) concluded that there was no difference between massage and acupuncture for pain relief at discharge,[56] but massage was more effective than acupuncture for pain relief at long-term follow-up. In terms of disability at short-term follow-up, massage was significantly more effective than acupuncture; however, at long-term follow-up, this difference was only marginally significant ($P = 0.05$). Moreover, there was no significant difference between acupuncture and self-

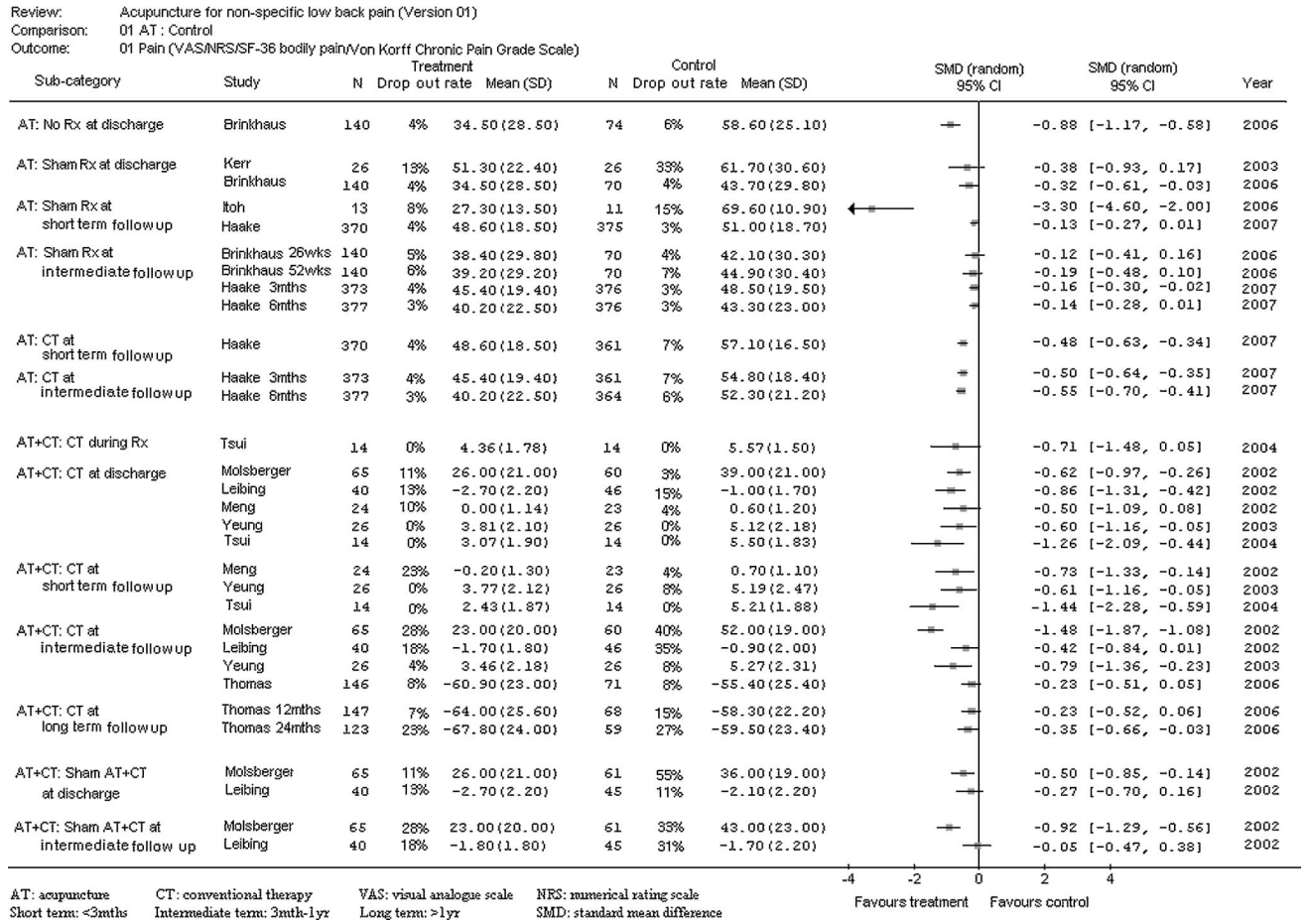

Figure 2. SMD of pain.

care for pain and functional disability at short/long-term follow-up.

Two low-quality studies concluded that chiropractic spinal manipulation was more effective than acupuncture,[66,67] for pain and functional improvement, at discharge.[66,67] However, both studies included less than 40 patients per group, did not report between-group statistical comparisons, and 1 study had a high dropout,[67] all of which makes the evidence unreliable (Tables 1, 2).

Acupuncture and Conventional Therapy *Versus* Conventional Therapy (n = 8). Two high-quality studies[11,20] and 5 low-quality studies[17,53,55,58,68] provided strong evidence that acupuncture combined with conventional therapy was more effective than conventional therapy alone for pain relief, and moderate evidence for functional disability,[11,53,54,58] at discharge or short-term/intermediate/long-term follow-up, respectively. Seven studies got high Van Tulder scores, but 3 of them had less than 40 patients per group,[17,53,54] and the other 2 had high dropouts at the intermediate follow-up,[55,58] despite both including group sizes of more than 40 patients (Tables 1, 2).

Acupuncture and Conventional Therapy *Versus* Sham Acupuncture and Conventional Therapy (n = 2). Two low-quality studies with high Van Tulder scores, more than 40 patients per group but large dropouts at intermediate follow-up, provided conflicting and unreliable evidence: 1 study (n = 126)[55] showed significant superior effects of acupuncture plus PT over sham acupuncture plus PT, on pain relief at discharge and intermediate follow-up. The other study (n = 100)[58] reported that acupuncture plus PT did not improve pain and function significantly compared with sham acupuncture plus PT at short/intermediate term follow-up (Tables 1, 2).

Effect Size

10/31 studies for pain (31 comparisons) and 9/26 studies for functional disability (26 comparisons) provided sufficient data for calculation of effect sizes for these respective outcomes. With regards to both pain and functional disability, in general, moderate to large effect sizes have been achieved in the comparison of acupuncture *versus* no treatment,[18] or acupuncture plus conventional therapy *versus* conventional therapy alone,[11,17,53,55,58] whereas other groups of comparisons generally achieved small to moderate effect sizes (Figures 2, 3).

Clinical Significance

The mean differences for functional disability could only be calculated from a few studies, therefore it was considered insufficient to judge the clinical significance of this outcome.

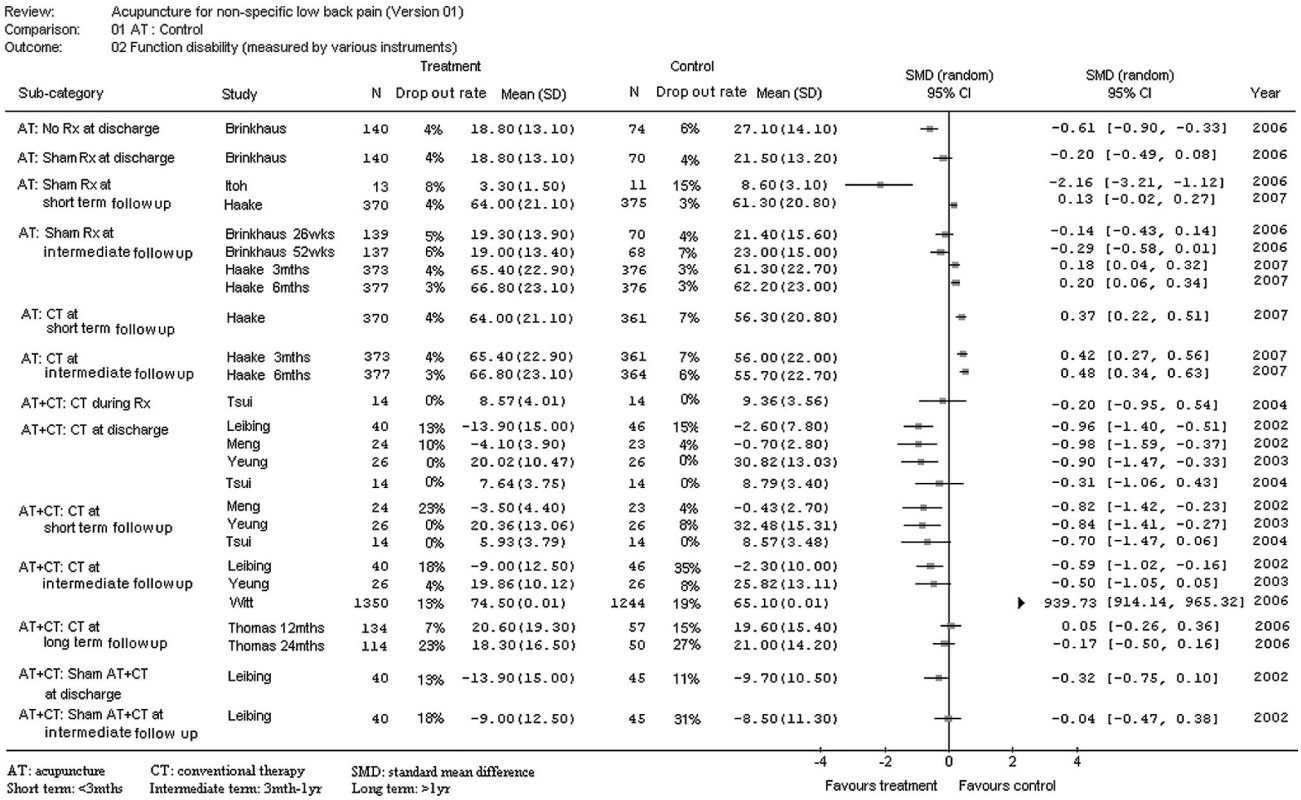

Figure 3. SMD of functional disability.

Fortunately, all of the included 23 studies measured pain intensity, 12 of which provided sufficient data for the calculation of mean difference between groups, 7 studies used VAS (0–100 mm), 3 used NRS (0–100 mm), 1 used Short Form-36 (SF-36) bodily pain dimension (0%–100%), and 1 used Von Korff Chronic Pain Grading Scale (0–10). All of the 12 studies (33 comparisons) favored acupuncture in terms of pain reduction. Twenty-four percent (8/33) of comparisons achieved the MCID (−20% or more) on pain reduction;[17–19,55,61,64] however, only 2 of them clearly achieved the MCID, *i.e.*, both limits of 95% CI of mean difference were greater than the MCID[19,55] (Figure 4).

■ Discussion

This review has provided strong evidence that there is no significant difference between acupuncture and sham acupuncture (superficial needle insertion at nonacupoints), for short-term and intermediate pain relief and functional improvement, which updates the previous evidence that favored acupuncture over sham acupuncture.[15,16] For other comparisons, the addition of the 6 RCTs[11,15–21] either strengthened or confirmed the previous conclusions, by providing moderate evidence favoring acupuncture over no treatment, strong evidence favoring acupuncture as an adjunctive therapy over conventional therapy alone, and conflicting evidence for acupuncture *versus* conventional therapy.

Given that our review has shown no difference between acupuncture and sham acupuncture, it is worth exploring the reasons for this result in more detail. Our review included additional studies published after the search dates of the earlier reviews,[15,16] 4 of which we classified as high quality and held significant weight in our qualitative analysis.[11,18,20,21] Another important difference was the fact when the studies were pooled,[15,16] over half were sham TENS studies (all of which we defined as unreliable[52,57,62,63]) and only 3 studies compared acupuncture to sham acupuncture alone or as an adjunct to some form of conventional care.[55,58,69] In our qualitative synthesis, we separated out these 2 latter comparisons to show strong evidence that acupuncture alone is not significantly different from sham acupuncture alone (based on the addition of 2 new trials,[18,21]), whereas the findings for acupuncture/sham acupuncture as an adjunct to conventional care[55,58] provide conflicting evidence.

This lack of difference between sham and real acupuncture raises a debate about how appropriate controls can be chosen. Four of the included studies used superficial needling outside meridians,[18,21,55,58] which has been argued to be as effective as deep needling at specific acupoints[45,58,70–72] and considered of therapeutic benefit in traditional acupuncture practice.[73,74] The recently developed nonpenetrating sham needles have been advocated as more appropriate controls.[75–77] Indeed, in this review, the only 1 study favoring real over sham acu-

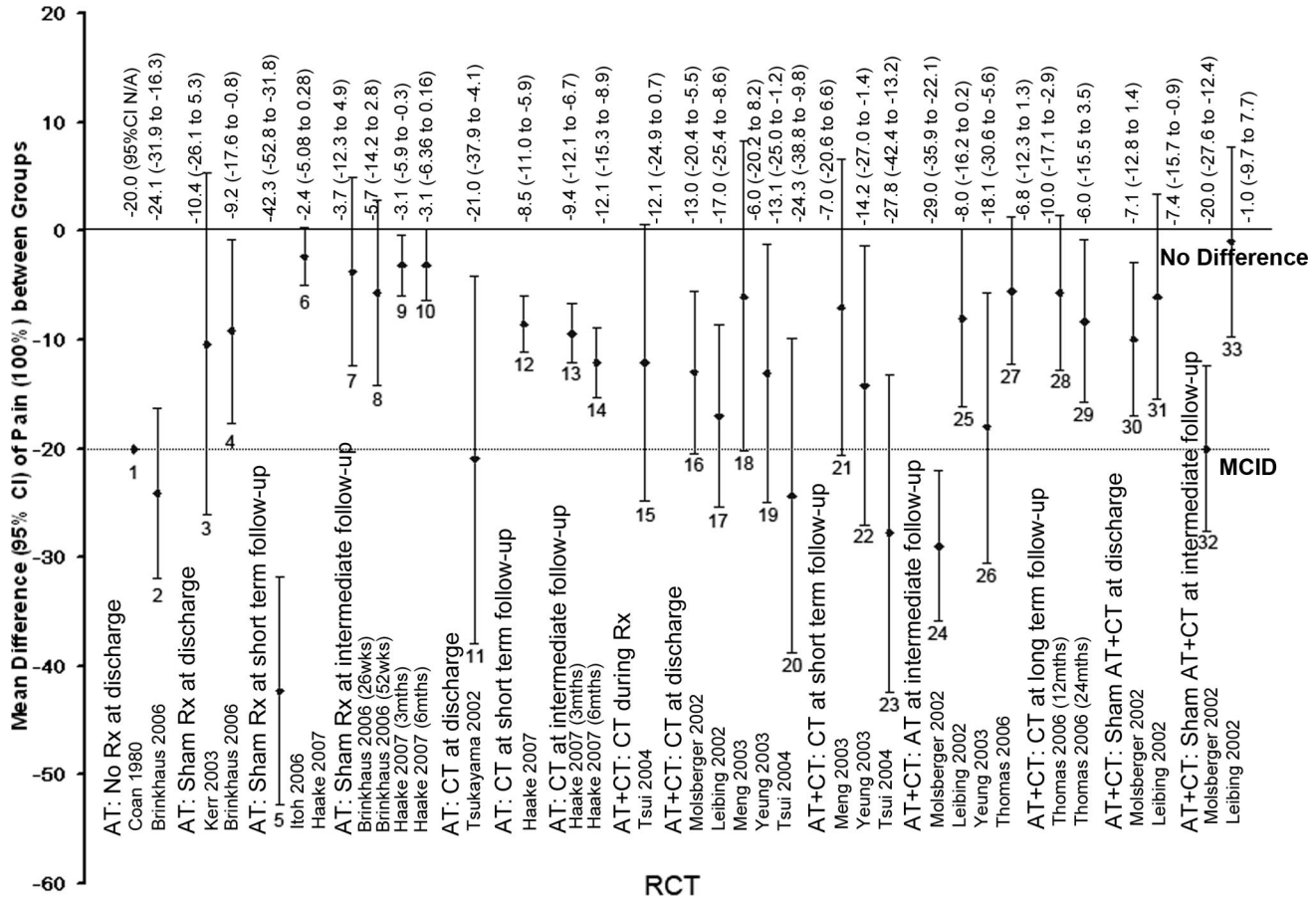

Figure 4. Mean difference (95% CI) of pain on VAS/NRS/SF-36 bodily pain/Von Korff CPGS (100%). Zero: as indicated by the upper solid line, suggests no difference between treatment and control group. Positive estimates favor control group; negative estimates favor acupuncture group. MCID (minimal clinically important difference, −20%): as indicated by the lower dashed line, suggests that values of the between-group changes greater than 20% (below the dashed line) are clinically significant. AT indicates acupuncture; CT, conventional therapy; N/A, not available; VAS, visual analogue scale; CPGS, chronic pain grade scale; NRS, numerical rating scale; SF-36, short form 36; Follow-up, follow the patients from the end of treatment.

puncture used a nonpenetrating needling as the control;[19] however, it is worth noting that in other clinical areas, studies using such controls have provided conflicting results.[78–81]

We were able to strengthen other comparisons, for example, acupuncture was superior to no treatment and as an adjunct to conventional care. We included an additional large high-quality trial[18] to the 2 small low-quality trials used by Furlan to support the superiority of acupuncture to no (acupuncture) treatment. In terms of acupuncture as an adjunct to conventional care, we were able to include 3 new RCTs (2 of which were large high quality trials and used standard medical care as the conventional care comparator[11,20]) with small to large effect sizes. It is of interest to note that in general, the most potent effect sizes in terms of pain and functional disability were observed in the comparison of acupuncture versus no treatment, or acupuncture as an adjunct to conventional therapy, from discharge to intermediate term follow-up. Whereas much smaller effect sizes were observed, in general, when making comparisons to sham acupuncture.

Given the plethora of treatments for LBP, it is important to contextualize the results of the current review with respect to current guidelines such as the European Guidelines.[22] The effects of acupuncture are equivalent to the effects sizes for treatments currently advocated (exercise, pain relief *e.g.*, NSAIDS, behavioral treatments).[82] Although the current review is unable to answer the question about acupuncture versus a completely inert and indistinguishable placebo control as in medication studies,[83] this is also the case for manipulation, which has a smaller effect size[82] and is advocated in the guidelines.[22]

There are some limitations to this review. Firstly, although it was carried out in nonspecific LBP, a few studies on mixed/unclear type of LBP were included,[68] and only studies on specific LBP, such as sciatica, were excluded. Secondly, it was limited to English studies only. However, many of the non-English articles *e.g.*, 29 RCTs in Chinese would have been excluded in our review because of the lack of valid/reliable or objective outcome measures. Finally, the measure of clinical effectiveness for pain in our review was set at 2 points

(or 30% relative to baseline), which correlates with a patient global improvement rating of "much improved" or "very much improved."[84,85] It has been suggested that a cut off of 50% would be more stringent, but as pointed out in the editorial by Rowbotham,[86] a 50% reduction in pain intensity corresponds to the highest level of patient impression of improvement. Given the accompanying lack of side effects of acupuncture for pain relief[87,88] and the consensus in LBP around 2 points (or 30%) as a indicator of real change from the patients perspective,[29,32,89] we feel that a choice of 2 points is a valid cut off for meaningful clinical change.

■ Conclusion

Based on the results of this review, acupuncture should be advocated for the treatment of chronic LBP and included in the European Guidelines for this condition, given the equivalent effect sizes to treatments currently advocated (exercise, NSAIDS, behavioral treatments vs. no treatment).[82] It is more difficult to make conclusions about acupuncture as an adjunct to conventional treatment as there is such a wide variety of treatments included, not all of which are evidence based. However, the evidence for acupuncture as a cost effective adjunct to standard medical care is clear cut and therefore should be advocated. The effectiveness of acupuncture alone in comparison with conventional therapies is conflicting and requires more research. Another major area for further work stems from the finding that acupuncture is not more effective than a physiologically active sham control.

Although the reporting and methodologic quality of the studies have been improved in recent years, in terms of detailed reporting of acupuncture treatment, larger sample sizes, longer-term follow-up, blinding and intention-to-treat analysis *etc.*, there is still lack of consensus (and thus guidelines) with regards to adequate acupuncture treatment (number of needles inserted, needle manipulation technique, treatment frequency and sessions, appropriate cointerventions *etc.*). We therefore suggest that future trials should focus on such areas where there are few or no trials to guide practice.

■ Key Points

- Both electronic and manual searches were made on RCTs in English, extended to January 10, 2008.
- Twenty-three included RCTs were divided into 5 comparison groups, based on which a best evidence synthesis was conducted. Effect size and clinical significance were determined on available data.

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