

# Review of randomised controlled trials comparing efficacy of acupuncture Vs no acupuncture for chronic non-specific low back pain.

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## Citation

S Memon, M Chawala, A Khanna. *Review of randomised controlled trials comparing efficacy of acupuncture Vs no acupuncture for chronic non-specific low back pain.* The Internet Journal of Orthopedic Surgery. 2008 Volume 13 Number 2.

## Abstract

### Study Design:

Systemic review of randomised controlled trials comparing efficacy of acupuncture Vs no acupuncture in non-specific chronic low back pain. Objective: Compare research methods and results. Background: There has been multiple trials to prove the efficacy of acupuncture in patients with non-specific chronic low back pain. We conducted review of randomised controlled trials comparing acupuncture Vs usual care with no acupuncture input. Methods: We identified 8 randomised controlled trials relevant to inclusion criteria. 3 were not focused on the topic and were excluded. Excluded articles were more about immediate pain relief after acupuncture, cost-effectiveness trial and was regarding other branch of Traditional Chinese medicine i.e.

Acupressure. Results: None of studies managed to prove dramatic improvement in chronic non-specific back pain, however, all 4 trials proved acupuncture is an effective treatment vs. no acupuncture. 2 trials reached to statistically significant levels, 1 proved long term benefit is more than short term effect and 1 trial with high power managed to reach to near statistically significant. Hence, acupuncture is a safe adjunct to conventional pain relief therapy.

## INTRODUCTION

Non-specific low back pain is one of costliest pain for National Health Service in United Kingdom. About 16% of adult population presents to general practise annually with back pain.<sup>1, 2</sup> Multitude of non-surgical therapies has been suggested in literature including acupuncture but there is no concrete evidence for the efficacy of the procedure to treat long standing non-specific back pain.<sup>3,4</sup>

Acupuncture is the famous branch of Traditional Chinese Medicine (TCM). It is being used by an estimated 2% of adult population in UK for various types of pain management.<sup>5</sup> Therefore, the purpose of this study is to conduct systemic reviews of randomised trials comparing acupuncture Vs conventional analgesics in chronic low back pain.

Sifting through the literature, we have been unable to find unanimous evidence about the efficacy of the treatment. Although, it has been used in other conditions like radicular back pain,<sup>6</sup> pregnancy,<sup>7</sup> anxiety and sleep disorders secondary to low back pain,<sup>9</sup> and spinal manipulations.<sup>8</sup>

Acupuncture has been practised in many different ways. Few of them described as Verum, Sham, and electrical stimulation of pins, intramuscular and periosteal acupuncture.<sup>9</sup>

## Figure 1

Table 1 Comparison of Methods

	Haake et al	Meng et al	Brikhaus et al	Thomas et al
Settings				
Design	RCT	RCT	RCT	RCT
Published (year)	2007	2003	2006	2006
Location	Germany	USA	Germany	UK
No. of centres	340	Multicentre	30	16
Funding	Insurance company	Arthritis Association	Insurance company	NHS
Participants				
Age	18 years+	60 years +	40-75 years	20-64 years
Pain duration	> 6 months	>12 weeks	> 6 months	4-52 weeks
Outcome Measures	@ 6 months VKC pain grade scale questionnaire and Back specific HFA questionnaire	@ 6 weeks Roland disability questionnaire+ Global transition score	@ 8 weeks Visual analogue score	@12 and 24 months SF-36 + Oswestry disability Index + McGill present pain index + Patient Satisfaction

## METHODS

**STUDY DESIGN AND OBJECTIVE**

This is a review of randomised trials comparing acupuncture Vs no acupuncture.

**CRITERIA FOR SELECTING STUDIES**

We sought trials that compared acupuncture to usual back pain care. We didn’t restrict age, sex or types of acupuncture. We didn’t consider trials of cost effectiveness, or comparing acupuncture with other complimentary therapies.

**SEARCH STRATEGIES FOR RELEVANT STUDIES**

We conducted a thorough search through major databases, i.e. MEDLINE, EMBASE and Allied and Complimentary medicine and managed to retrieve 274 articles. Our search terms were acupuncture, lumbar and lumbosacral region, pain, backache and low back pain. Our limitations were articles in English language and between the years 2003 and 2005. Review of abstracts identified 8 randomised controlled trials. Last Cochrane review was in 2004 on this topic.<sup>10</sup> Out of 8, 3 articles were not focused on the topic and were excluded.<sup>11•12•13•14</sup>

**Figure 2**

Table 2 Comparison of treatment interventions

	Haake et al	Meng et al	Brinkhaus et al	Thomas et al
Acupuncture Group	10 sessions of 30 minutes in 5 weeks (5 extra session if no response)	10 sessions	12 sessions over 8 weeks	10 sessions over 3 months
Sham/ Minimal acupuncture	10 sessions of 30 minutes in 5 weeks	-	12 session over 8 weeks	-
Control/ conventional therapy.	10 sessions in 5 weeks of back exercises, and NSAIDs.	NSAIDs, muscle relaxants, Paracetamol, back exercises	NSAIDs	Massage, Physiotherapy, NSAIDs, Back exercises.

**RESULTS**

**REPORT FUNDING**

Two studies were funded by insurance and one by NHS (government) and one was funded by Arthritis Association (New York Chapter)

**SUBJECT SELECTION**

All 4 studies were multi centred trials conducted in United States of America, United Kingdom and Germany. Investigators selected different age groups of adult population from 18 to 75 years of age with history of chronic low back pain more than 4 weeks to 8 years. They excluded patients with spinal tumour, infection, and fracture or with any neurological deficit (table 1) or spinal cord compression or deformity of the spine.

**RANDOMISATION**

All 4 studies used computer-generated randomisation to allocate patients into treatment groups. Baseline characteristics were well balanced. Haake et al used 1:1:1 but rest of the investigators preferred to 2:1 randomisation to balance the skills of acupuncturists. All of these studies were based on questionnaires and telephone interviews. Thomas et al couldn’t blind their study because of “pragmatic reasons” but rest of three studies were blinded. Haake et al and Meng et al also assessed their blinding in their questionnaires. It is not very clear whether all patients received their allocated sessions or not. In general, 10/337 in Haake’s<sup>17</sup>, 1/160 in Thomas’<sup>18</sup>, 27/147 in Brinkhaus’<sup>19</sup>, 3/28 in Meng’s<sup>20</sup> study didn’t get the active acupuncture treatment. Whether they were included in the final intention to treat analysis is not entirely clear except in Haake’s study where unblinded patients were considered non-responders.

**INTERVENTION**

All 4 studies compared acupuncture Vs no acupuncture. Haake et al and Brinkinhaus et al compared 3 groups namely acupuncture, sham (minimal acupuncture) and no acupuncture (conventional therapy). However, Meng et al and Thomas et al didn’t consider sham acupuncture since it is superficial needling at non-acupuncture points.

**MEASUREMENTS OF OUTCOMES**

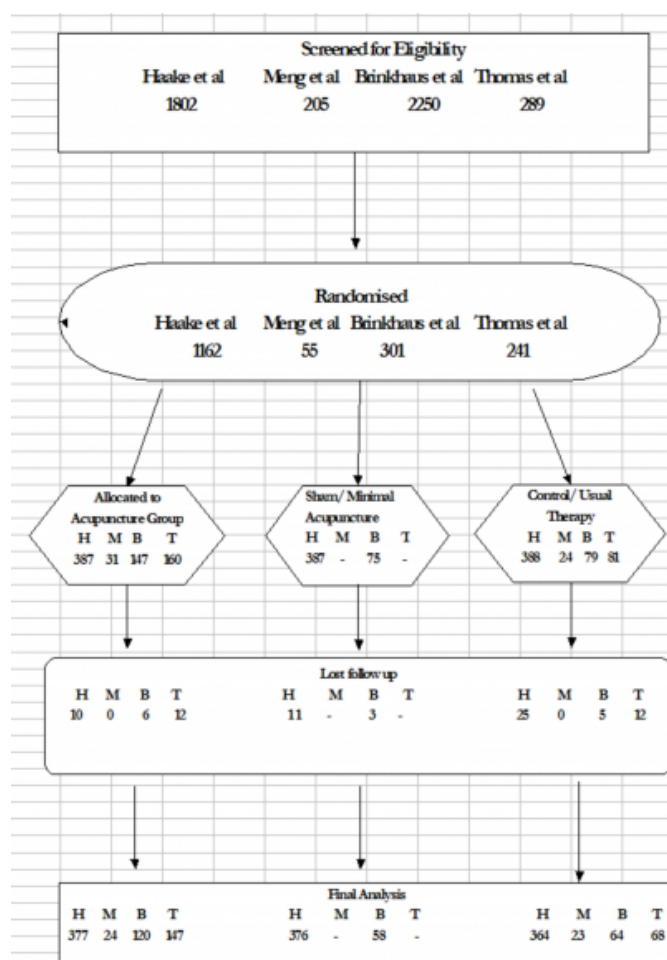
All 4 studies measured multiple outcomes using validated tools for back specific disability, pain, general function, and psychological function (Table 1).

Haake used Von Korff Chronic Pain Grade Scale (VKCPGS) Questionnaire where 33% improvement or 3-point improvement considered statistically significant or 12% improvement on back-specific Hanover Functional Ability (HFA) Questionnaire. This study proved 3.4% (CI –3.7-10.3%; P value-0.39) improvement in Verum vs. sham acupuncture. However, Verum vs. conventional therapy shown considerable improvement of 20.2%(CI13.4%-26.7%; P value-0.001) and sham vs. conventional therapy were 16.8%(CI 10.1%-23.4%; P value 0.001).

Meng et al used Roland Disability questionnaire as main outcome measure where 4-point reduction is significant. They managed to get 4.1-point reduction at week 6 Vs 0.7 point with conventional therapy. He also used global transition score.

**Figure 3**

Table 1 Flow chart of screening, randomisation, Lost follow up and final analysis.



Brinkhaus et al used modified version of pain questionnaire published by German society for study of pain but primary outcome measure was Visual Analogue Scale (VAS). 40 points change considered significant in VAS. They found 28.7±30.2 mm improvement in acupuncture group, 23.6±31mm in minimal (sham) acupuncture and 6.9±22 mm in waiting list patients who were on conventional therapy.

Thomas et al used SF-36 (main outcome measure), Oswestry disability index (ODI), McGill present pain index, safety and patient satisfaction. At 12 months, they found 30.8 points reduction in acupuncture and 30.4 points in patients on conventional therapy. This interventional effect was statistically more significant at 24 months at 8 points between acupuncture and no acupuncture (>5 points is significant in SF-36) as compared to 5.6 points at 12 months. Therefore, shown strong evidence of small effect at 24 months but weak evidence of some effect of acupuncture at 12 months.

## DISCUSSION

### CRITICAL APPRAISAL

Haake et al study is one of the biggest and vigorous trials carefully conducted on acupuncture in chronic low back pain. They managed to prove considerable difference between acupuncture vs. guideline based conventional therapy. They managed to segregate physiologic effect from psychological effect by comparing Verum with sham acupuncture which further accentuates the credibility of the trial and understanding of the way acupuncture works. Positive points would be high power, low drop out rates and blinding checks. Negative points can be overtly poor results with conventional therapy.

Meng et al study is the smallest of all 4. Few positives are patients being sole assessors of their symptoms; similarly cross over of patients after the completion of the study did prove the symptom improvements after the treatment. It also reduces the confounding of acupuncture and same pain relief as of acupuncture group further confirms the findings of the acupuncture group. Negative points were low power, needle improvement was mixed with electric stimulation, patients with buttock and leg pain (? Spinal/ vascular) weren't excluded. On the other hand, 3 patients were excluded because they couldn't fill in the forms properly and finally, high loss of follow up.

Brinkhaus et al again presented with similar results. They managed to prove statistically significant difference between acupuncture and no acupuncture but no difference between two types of acupuncture. Positive points of this study are well-balanced baseline characteristics and again cross over to prove the results further. It was a big multicentre trial but was conducted on outcome measure of limited sensitivity and specificity. They later also took sham acupuncture as placebo but later proven to be wrong and ethically patients were informed of kind of acupuncture they will get after being randomised, though this did help in blinding.

Thomas et al study produced few surprising results that acupuncture produces more long-term results than short term. Technically, well organised study with well-predicted drop out rates and compensating power analysis. 2:1 randomisation allowed to accommodate the difference of acupuncturist's skills but this did tipped the balance towards acupuncture. Few negatives include open (unblinded) trial, "individualizing" the patients (extra 5 acupuncture sessions was provided if pain is not better), all

“off work” patients were offered acupuncture and statistically low power but then re recruiting of patients to improve the power.

In conclusion, none of these studies could confirm dramatic improvements in chronic low back pain after acupuncture therapy in short or long term despite of big power but few of them managed to reach statistically significant confidence intervals.

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