

## Randomised trial of acupuncture compared with conventional massage and “sham” laser acupuncture for treatment of chronic neck pain

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### Abstract

**Objectives** To compare the efficacy of acupuncture and conventional massage for the treatment of chronic neck pain.

**Design** Prospective, randomised, placebo controlled trial.

**Setting** Three outpatient departments in Germany.

**Participants** 177 patients aged 18-85 years with chronic neck pain.

**Interventions** Patients were randomly allocated to five treatments over three weeks with acupuncture (56), massage (60), or “sham” laser acupuncture (61).

**Main outcome measures** Primary outcome measure: maximum pain related to motion (visual analogue scale) irrespective of direction of movement one week after treatment. Secondary outcome measures: range of motion (3D ultrasound real time motion analyser), pain related to movement in six directions (visual analogue scale), pressure pain threshold (pressure algometer), changes of spontaneous pain, motion related pain, global complaints (seven point scale), and quality of life (SF-36). Assessments were performed before, during, and one week and three months after treatment. Patients’ beliefs in treatment were assessed.

**Results** One week after five treatments the acupuncture group showed a significantly greater improvement in motion related pain compared with massage (difference 24.22 (95% confidence interval 16.5 to 31.9),  $P=0.0052$ ) but not compared with sham laser (17.28 (10.0 to 24.6),  $P=0.327$ ). Differences between acupuncture and massage or sham laser were greater in the subgroup who had had pain for longer than five years ( $n=75$ ) and in patients with myofascial pain syndrome ( $n=129$ ). The acupuncture group had the best results in most secondary outcome measures. There were no differences in patients’ beliefs in treatment.

**Conclusions** Acupuncture is an effective short term treatment for patients with chronic neck pain, but there is only limited evidence for long term effects after five treatments.

### Introduction

Neck pain is a common complaint with a point prevalence from 10% to 18% and lifetime prevalence from 30% to 50%. In many cases symptoms persist, causing severe discomfort and inability to work.<sup>1 2</sup> Neck pain is associated with limited cervical spine mobility.<sup>3</sup> Frequent concomitant symptoms are headache, vertigo, visual disorders, tinnitus, and vegetative symptoms (sweating, dizziness, nausea).<sup>4 5</sup> Common treatment consists of drugs, massage and other manual treatments, physiotherapy and exercise, local and epidural injections, and patient education.<sup>6 7</sup> Systematic reviews have shown that the efficacy of these interventions remains questionable.<sup>7 8</sup> Current treatment increasingly includes complementary methods, of which acupuncture is one of the most common.<sup>9</sup> There is, however, a lack of evidence to support acupuncture as an effective treatment for chronic neck pain.<sup>10-12</sup>

We compared the efficacy of acupuncture with conventional massage and “sham” laser acupuncture for the treatment of neck pain.

### Methods

#### Study design

The study was a randomised, placebo and alternative treatment controlled clinical trial performed at three outpatient departments at the universities in Munich and Würzburg, Germany, from 1996 to 1999.

#### Participants

Patients were consecutively preselected by the doctors of the three outpatient departments, who were informed about the inclusion and exclusion criteria. Patients who were eligible and willing to participate in the study were then assessed by an independent examiner. This assessment included a detailed physical examination and collection of baseline data. The main inclusion criteria were that patients had had a painful restriction of cervical spine mobility for longer than one month and that they had not received any treatment in the two weeks before entering the study. Patients who had undergone surgery or those with dislocation, fracture, neurological deficits, systemic disorders, or contraindications to treatment were excluded.

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Neck pain was classified according to the system of Schöps and Senn on the basis of history, characteristics of pain, manual examination, and radiological findings.<sup>13</sup> Patients' conditions were defined as the myofascial pain syndrome (pain and limited mobility associated with myofascial triggerpoints),<sup>14</sup> the irritation syndrome (diffuse, intense pain with difficult access for manual examination), or segmental dysfunction (segmental hypomobility revealed by manual examination and functional radiograph analysis). The diagnosis was confirmed by a second assessor. Informed consent was obtained, and the study was approved by the local ethics committees.

### Randomisation

Participants were randomly allocated to acupuncture or massage or sham laser acupuncture. A block randomisation stratified for two centres was performed by using a validated software program (PC Random, Biometric Center for Therapeutic Studies, Munich). Patients were told before randomisation that one of the three treatments might be a sham procedure.

### Treatment protocols

Patients were treated five times over three weeks. Each treatment lasted 30 minutes. Acupuncture and sham laser acupuncture were performed by four experienced, licensed medical acupuncturists. Massages were performed by five experienced physiotherapists. Patients took no concomitant analgesics. Patients who rated their pain as over 20 on the visual analogue scale (0-100) or who had an inconvenient restriction of mobility at the primary study end point were referred for physiotherapy during follow up.

**Acupuncture**—Acupuncture was performed according to the rules of traditional Chinese medicine, including diagnostic palpation to identify sensitive spots.<sup>15</sup> Remote and local acupuncture points were selected individually on the affected meridians. Relevant ear acupuncture points were included. In addition local myofascial triggerpoints were treated with the technique of dry needling to elicit a local twitch response of muscles.<sup>14 16</sup> Criteria for point selection are described in detail.<sup>15-17</sup> The most commonly used points were SI3, UB10, UB60, Liv3, GB20, GB34, TE5, and the ear point "cervical spine." Active myofascial triggerpoints were located predominantly in the musculus trapezius (nearby GB20) and levator scapulae (nearby SI14).

**Massage**—Patients were treated with conventional Western massage. Techniques included effleurage, petrissage, friction, tapotement, and vibration.<sup>18</sup> Mode and intensity were chosen by the physiotherapist in accordance with the patient's condition and diagnosis as usual in clinical routine. Spinal manipulation and non-conventional techniques were not performed.

**Placebo**—Sham laser acupuncture was performed with a laser pen, which was inactivated by the manufacturer (Laser Pen, Seirin International, Fort Lauderdale). Only red light was emitted. Patients were not informed about the inactivation of the laser pen. To strengthen the power of this sham procedure, visual and acoustic signals common for this type of laser pen accompanied the red light emission. Criteria for selection of points were identical with those used in the acupuncture group, including palpation of acupuncture points for diagnostic reasons. Every point was treated

for 2 minutes, with the pen at a distance of 0.5-1 cm from the skin.

### Assessments

Assessments were performed by a blinded observer before the intervention (M1), immediately after (M2) and three days after (M3) the first treatment, and immediately after (M4) and one week after (M5, primary end point) the last treatment. Follow up included an assessment at three months (M6, secondary end point). Patients were requested not to reveal any information about their treatment during assessment.

To evaluate the adequacy of control treatments we assessed patients' beliefs about the treatment.<sup>19</sup> After randomisation and before the first treatment they had to answer four questions on a 100 point visual analogue scale: How confident do you feel that this treatment can alleviate your complaint? How confident would you be in recommending this treatment to a friend who suffered from similar complaints? How logical does this treatment seem to you? How successful do you think this treatment would be in alleviating other complaints?

### Outcome measures

**Primary outcome measure**—The primary outcome measure was the change in the maximum pain related to motion, irrespective of the direction of movement, evaluated before (M1) and one week after (M5) intervention. Patients were asked to move their head in the most affected direction and to score the intensity of pain on a 100 point visual analogue scale.

**Secondary outcome measures**—We measured the active range of motion with a 3D ultrasound real time motion analyser (Zebris Medizintechnik, Tübingen, Germany). It is a valid and reliable method to assess cervical mobility.<sup>20</sup> We measured the range of six cervical spine movements (flexion, extension, rotation right/left, lateral flexion right/left). In addition, patients used a visual analogue scale to score the intensity of direction related pain for each of the six directions. We quantified the pressure pain threshold bilaterally at three anatomically defined sites (levator scapulae, trapezius descendens, paravertebral of the 6th cervical spine) and the individual maximum point using a digital pressure algometer.<sup>21</sup> Two readings on each site were performed. We recorded changes of spontaneous pain, motion related pain, and global complaints on a seven point scale one week and three months after treatment. Patients were asked: "Did the severity of your spontaneous pain (motion related pain, global complaints) change after treatment?" If they answered yes, they were asked if the pain had improved or worsened and whether the change was slight, marked, or extreme. To assess quality of life the patients completed the SF-36 health survey.<sup>22</sup>

### Statistical analyses

Our intention was to analyse 52 patients per group, which, given a standard deviation of 18, would have provided 80% power at the 5% significance level to detect a 10 point difference in the mean change of motion related pain. This calculation was based on a pilot study that compared acupuncture with sham laser on immediate changes of motion related pain after a single treatment. We estimated a drop out rate of 20%

**Table 1** Characteristics of 177 patients with chronic neck pain included in trial

	Acupuncture (n=56)	Massage (n=60)	Sham laser (n=61)
Mean (SD) age (years)	52.3 (13.3)	52.7 (11.5)	52.2 (13.2)
Women	39	38	40
Whiplash	17	16	23
Myofascial pain syndrome	35	45	49
Duration of pain >5 years	23	24	28
Slow onset	36	47	45
Concomitant symptoms*:			
None	9	13	10
1-3	26	24	23
>3	20	22	26
History of treatment:	56	60	61
Massage	45	44	47
Fango (warm pack)	44	44	35
Physiotherapy	40	40	39
Chiropractic	25	32	30
Infiltration with local anaesthetics	18	25	23
Relaxation methods	18	23	19
Acupuncture	14	23	21
Psychological pain therapy	5	5	6

\*Headache, low back pain, vertigo, tinnitus, fatigue, sensitivity to noise and light, lack of motivation, nausea, unspecific visual disorders.

and therefore aimed to recruit 200 patients. However, the study was terminated after we recruited 177 patients because the study period was over and the drop out rate was mostly below 20%, leading to a sufficient number of eligible patients for analyses.

Statistical analyses of all study variables were based on intention to treat analysis. For analyses of range of motion and direction related pain we calculated mean values on the basis of the data for six movement directions (score). We used parametric variance to test quantitative variables for comparisons of mean differences, which were approximately normally distributed, followed by pairwise comparisons. For the main outcome measure and quantitative parameters

we adjusted for multiple comparisons to keep the significance level to 0.05. We tested hypotheses on qualitative data with  $\chi^2$  tests or Fisher's exact test. All calculations were carried out with the SAS software package, version 6.12.

## Results

### Randomisation and progress through the trial

Of 182 patients referred for the first assessment, five did not meet entry criteria; 177 patients were included in the trial. Baseline characteristics of the study sample were equally balanced between groups for most variables, but there was some difference with regard to myofascial pain (table 1). In all three groups most patients believed in the potential benefit of the treatments. The figure shows the progress of patients through the trial and withdrawal from study.

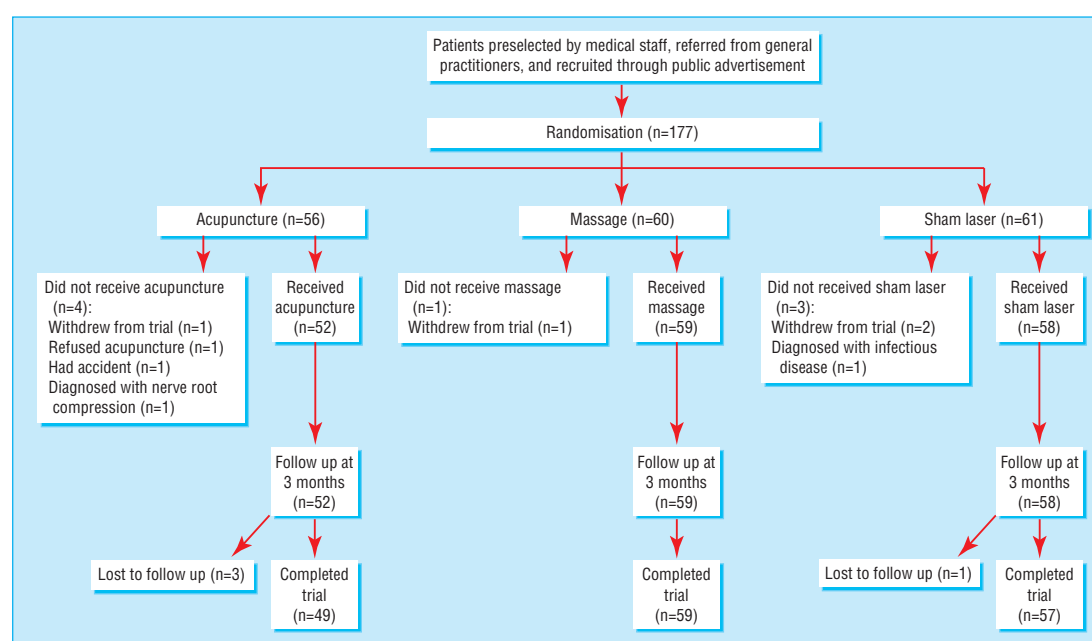
### Main outcome measure

The results of the baseline measurements are shown in table 2. The mean improvement one week after intervention is shown in table 3. The reduction in pain related to motion was significantly greater in the acupuncture group compared with the massage group ( $P=0.0052$ ) but not compared with sham laser ( $P=0.327$ ). Differences between acupuncture and massage or sham laser were more distinct in the subgroup who had had pain for longer than five years and in patients with the myofascial pain syndrome (table 3).

Pain related to motion improved by more than 50% compared with baseline in 29/51 (57%) patients who received acupuncture compared with 18/57 (32%) patients who received sham laser and 14/57 (25%) patients who received massage ( $\chi^2$  test  $P=0.008$ ).

### Secondary outcome measures

Table 4 shows mean changes in secondary outcome measures and comparisons between treatment groups. The results for secondary outcome measures were



Participants' progress through trial and withdrawals

**Table 2** Baseline measurement (M1) of primary and secondary outcome measures. Data are expressed as mean (SD) values

Outcome measures	Acupuncture (n=56)	Massage (n=60)	Sham laser (n=61)
Pain related to motion (VAS)	54.15 (21.91)	54.71 (23.46)	57.15 (26.71)
Range of motion (degrees)*	277.9 (52.5)	287.8 (50.3)	286.5 (49.2)
Pain related to direction (VAS)†	33.87 (16.06)	34.88 (19.55)	35.82 (21.10)
Pressure pain threshold (kg/cm²)‡	1.07 (0.57)	1.07 (0.58)	1.05 (0.57)
Health related quality of life (SF-36)§:			
Role physical	46.50 (41.65)	41.82 (36.61)	39.04 (42.26)
Pain index	38.82 (17.38)	36.70 (17.06)	39.21 (17.21)

VAS=visual analogue scale.

\*For analyses of range of motion, data of six movement directions were added for each patient.

†Range 0-100. Scores for six movement directions averaged for each patient (score also includes less painful movement directions).

‡Measurements on individual maximum point. Results for three other sites were similar.

§Only two of eight scales showed limitations. Range of scores is 0-100; 0 indicates maximum limitation.

similar to those for the primary outcome measure. The acupuncture group achieved the best results in most of the secondary outcome measures, including significant differences compared with massage in pain related to motion and direction immediately and one week after treatment. Three months after treatment these differences were comparatively small and no longer significant. However, significantly more patients in the acupuncture group considered their pain (spontaneous, motion related) and global complaints improved three months after treatment compared with patients in the massage group ( $\chi^2$  tests). We found no significant differences between groups in pressure pain threshold.

Baseline evaluation of quality of life related to health showed limitations in only two of eight scales (role physical, pain index). After treatment these two scales were improved in all groups, without significant differences between groups. A total of 119 patients (67%) were referred to physiotherapy during follow up. There were no differences between groups.

### Side effects

Seventeen (33%) participants reported mild reactions after needle insertion during acupuncture, mainly slight pain or vegetative reactions (sweating, low blood pressure). After a short rest they agreed to continue the

**Table 3** Primary outcome measure: improvement of pain related to motion one week after treatment compared with baseline measurements. Group comparison and subgroup analyses

	Mean improvement on VAS (95% CI)	P value for comparison*
<b>All participants</b>		
Acupuncture (n=51)	24.22 (16.5 to 31.9)	—
Massage (n=57)	7.89 (0.6 to 15.2)	—
Sham acupuncture (n=57)	17.28 (10.0 to 24.6)	—
Acupuncture v massage	16.32 (4.4 to 28.3)	0.0052
Acupuncture v sham laser	6.93 (−5.0 to 18.9)	0.327
<b>Patients with the myofascial pain syndrome</b>		
Acupuncture (n=34)	30.05 (20.4 to 39.7)	—
Massage (n=43)	7.23 (−1.3 to 15.8)	—
Sham acupuncture (n=45)	19.02 (10.8 to 28.2)	—
Acupuncture v massage	22.8 (8.3 to 37.3)	0.0012
Acupuncture v sham laser	11.0 (−3.2 to 25.2)	0.1480
<b>Patients with pain &gt;5 years</b>		
Acupuncture (n=23)	31.87 (21.9 to 41.8)	—
Massage (n=23)	13.52 (3.6 to 23.5)	—
Sham acupuncture (n=27)	17.15 (7.9 to 26.3)	—
Acupuncture v massage	18.35 (2.4 to 34.3)	0.0216
Acupuncture v sham laser	14.7 (0.6 to 30.6)	0.0617

VAS=visual analogue scale. \*Dunnett's test.

treatment. Similar mild reactions were seen in four (7%) in the massage group and 12 (21%) in the sham laser group. No serious adverse reactions were observed.

## Discussion

Our results show that acupuncture is a safe form of treatment for people with chronic neck pain and offers clear clinical advantages over conventional massage in the reduction of pain and improvement of mobility. Acupuncture was most effective in people who had had pain for over five years and in those with the myofascial pain syndrome. Such patients can be identified from their case histories and a detailed physical examination.

Our study population generally had “non-specific neck pain,” which includes most patients suffering from chronic neck pain.<sup>23 24</sup> Between 55% and 90% of patients with chronic neck pain have the myofascial pain syndrome<sup>4 14</sup> and 20% to 50% have suffered a whiplash injury.<sup>5</sup> There were no significant differences between groups in the primary outcome measure (pain related to motion) and most of the secondary outcome measures three months after treatment. This is consistent with the results of recent systematic reviews that show that a single treatment approach in chronic pain does not result in long term effects.<sup>7 8</sup> However, results of the qualitative verbal rating scales, which express a more subjective change of pain and global complaints, might indicate longer lasting benefits of acupuncture. Conventional massage had only a weak effect on chronic neck pain. This is in agreement with recent reviews indicating a lack of evidence for the efficacy of massage, although it is one of the most common forms of treatment.<sup>2 18</sup>

Previous trials of acupuncture for neck pain have had contradictory results. In a systematic review of 14 acupuncture trials, White and Ernst found no evidence for efficacy, with outcomes equally balanced between positive and negative.<sup>10</sup> The authors judged methodological quality of the studies as disappointing. In a more recent review, Smith et al assessed the analgesic efficacy of acupuncture for neck and back pain. Using a newly developed tool to measure validity of findings of randomised clinical trials, they found no convincing evidence for the analgesic efficacy of acupuncture, and, again, the quality of most trials was poor.<sup>12</sup> In contrast with previous studies our trial had a large sample size, adequate measures evaluated by blinded observers, blinded patients for placebo control, individual acupuncture treatment by more than one licensed acupuncturist, data analyses by an independent institution, follow up assessments, and documentation of drop outs and adverse events.

We chose sham laser acupuncture because it does not activate somatosensory receptors and laser acupuncture is a well known method. We were surprised by the results of sham laser acupuncture compared with massage. They could be explained by an enhanced placebo effect, but the assessment of credibility showed no differences between therapies before treatment. Sham laser acupuncture, however, does not really resemble needle acupuncture. Consequently, non-specific acupuncture effects can only be estimated. Also, sham laser was probably not an inert



control because participants might have benefited from palpation of acupuncture points, performed before treatment to select acupuncture points.

Participants received only five treatments because we did not want to treat patients with chronic pain with placebo for longer for ethical reasons. According to traditional Chinese medicine about 10 sessions would be more appropriate.<sup>15</sup> Future research is necessary to evaluate the optimum number of treatments.

It has become clear from our results that placebo controlled studies should include a third group with alternative treatment or without treatment for improved classification of the effects of acupuncture because a true placebo procedure, including blinding of acupuncturists, does not exist for needle acupuncture studies.<sup>11–25</sup> The results do not elicit the specificity of acupuncture points or physiological mechanisms.

## Conclusion

We conclude that acupuncture can be a safe form of treatment for patients with chronic neck pain if the objective is to obtain relief from pain related to motion and to improve cervical mobility. As neck pain may be a chronic condition with considerable socioeconomic impact single forms of treatment may be inadequate, and acupuncture merits consideration.

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Contributors: DI coordinated the study, wrote the case report form, analysed the data, and wrote the paper. NB had the original idea, prepared the grant application, and coordinated the study in the first phase until 1997. HM contributed to the coordination and running of the study in Würzburg. AK coordinated the study in Würzburg and contributed to the data analysis and writing of the paper. MN contributed to the original idea and the grant application and coordinated the study in

**Table 4** Secondary outcome measures. Improvement in 165 patients with chronic neck pain immediately after (M2) and three days after (M3) first treatment, immediately after (M4) and one week after (M5, primary end point) last treatment, and at three month follow up (M6) compared with baseline measurements and comparison between groups by treatment. Figures are means (SD) unless indicated otherwise

	Acupuncture	Massage	Sham laser	Difference between groups*	
				Acupuncture v massage	Acupuncture v sham laser
Pain related to motion (improvement on VAS 0-100)†					
M2	7.8 (21.1)	7.2 (21.5)	7.3 (21.2)	0.981	0.984
M3	12.7 (22.2)	5.4 (24.7)	11.4 (21.4)	0.168	0.937
M4	25.3 (22.6)	12.7 (29.5)	19.2 (26.5)	0.027	0.388
M6	17.4 (29.7)	14.4 (31.9)	17.4 (26.4)	0.823	1.000
Range of motion (degrees)‡					
M4	19.6 (36.3)	6.2 (25.3)	12.9 (25.1)	0.034	0.384
M5	19.8 (37.9)	5.1 (22.2)	8.7 (33.0)	0.031	0.125
M6	8.9 (30.1)	5.5 (37.2)	3.5 (29.8)	0.815	0.609
Pain related to direction (improvement on VAS 0-100)‡					
M4	16.9 (15.6)	5.6 (15.3)	10.2 (18.5)	0.001	0.066
M5	17.3 (18.0)	3.1 (15.0)	11.4 (18.7)	0.0001	0.138
M6	15.0 (14.3)	8.1 (21.8)	11.2 (19.3)	0.113	0.486
Pressure pain threshold (kg/cm²)§					
M4	0.06 (0.58)	0.04 (0.50)	−0.03 (0.51)	0.971	0.558
M5	−0.02 (0.54)	−0.09 (0.62)	−0.07 (0.52)	0.696	0.864
M6	0.19 (0.77)	0.05 (0.59)	0.03 (0.62)	0.447	0.368
Spontaneous pain (rating scale)¶					
M5	35/51 (69%)	28/56 (50%)	30/56 (54%)	0.150	0.242
M6	33/47 (70%)	25/57 (44%)	28/56 (50%)	0.015	0.056
Pain related to motion (rating scale)¶					
M5	44/52 (85%)	33/58 (57%)	34/57 (60%)	0.002	0.012
M6	38/48 (79%)	29/57 (51%)	34/57 (60%)	0.007	0.089
Global complaints (rating scale)¶					
M5	46/52 (88%)	32/58 (55%)	39/57 (68%)	0.001	0.040
M6	39/48 (81%)	32/57 (56%)	38/57 (67%)	0.022	0.225
Role physical**					
M5	8.06 (31.9)	12.37 (34.4)	0.00 (23.6)	0.797	0.498
M6	0.83 (41.3)	4.95 (37.3)	5.83 (34.5)	0.865	0.825
Pain index**					
M5	8.41 (20.2)	10.15 (17.3)	8.85 (16.9)	0.843	0.989
M6	13.76 (22.4)	14.64 (22.1)	15.67 (21.5)	0.971	0.870

VAS=visual analogue scale.

\*P values. Parametric variance analytic models used for comparison of improvements of all quantitative variables with adjustment according to Dunnett. For comparison of qualitative variables (rating scale)  $\chi^2$  tests were used without adjustment for multiple comparisons. Repeated measurements at different time points were performed without further adjustment.

†Data from six movement directions added for each patient. To analyse changes of range, differences calculated by subtracting results for each patient after treatment from those before treatment.

‡Ratings of six movement directions averaged for each patient; less painful movement directions included in score. To analyse changes of direction related pain, differences were calculated by subtracting results for each patient after treatment from those before treatment.

§Measurements on individual maximum point. Results for three other sites were similar.

¶No of patients improved v treated (percentage); 7 point rating scale reduced to 3 point scale (improvement, no change, worsening).

\*\*Only two of eight scales showed limitations in SF-36 before treatment.

Würzburg. MK had the main responsibility for the data analyses and contributed to writing the paper. JG, AB, ES, and PS supported and contributed to the planning of the project, the grant application, the study running, and the publication. DI and MK and guarantors for the study.

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## What is already known on this topic

Acupuncture is a widespread complementary treatment

Evidence from trials have given conflicting results on its use in the treatment of neck pain because of methodological shortcomings and because effects were compared either with alternative treatments or with different sham procedures imitating acupuncture, but not both

## What this study adds

Compared with sham laser acupuncture and massage, needle acupuncture has beneficial effects on mobility and pain related to motion in patients with chronic neck pain

Acupuncture was clearly more effective than massage, but differences were not always significant compared with sham laser acupuncture

Acupuncture was the best treatment for patients with the myofascial syndrome and those who had had pain for longer than five years

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## Commentary: Controls for acupuncture—can we finally see the light?

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Irnich et al are to be congratulated for performing this rigorous trial. Funding is not easy to obtain for trials of acupuncture, so a sample size of 177 is considered large in this specialty. The result is hard to interpret. Advocates of acupuncture will call it a “positive” result. Opponents will argue that acupuncture is no better than placebo and that a similar trial on low back pain gave the opposite result.<sup>1</sup> We are left to speculate on whether acupuncture has specific efficacy in neck pain. A response rate of 57% would certainly be typical of an effective treatment in acute and chronic pain,<sup>2</sup> but even if this trial had shown a significant effect of acupuncture over sham laser acupuncture, we would still be unsure of the size of the non-specific component related to the needle.

Sham laser acupuncture was a good choice of control when this trial was designed. It can be considered inert, and it controls for the concept of having “acupuncture” in the mind of a participant who recognises it as a valid form of treatment. We cannot be sure, however, that this would equate to controlling for the concept of needle insertion. In the past, researchers have focused on the concept of acupuncture points, and, ironically, controls were often chosen simply by missing the real point—that is, inserting needles at sites not classically described as acupuncture points. The pressure stimulus applied to the nervous system from a solid needle, however, in the absence of direct impingement on a nerve bundle, is likely to be comparable at any soft tissue site within the same region, so the stimulus applied in such trials was virtually identical in the real and control groups. The response rate seen with such controls often reaches 50%. Reviews that fail to take this into account, by assuming that penetrating sham controls represent inert placebos, are open to criticism.<sup>3</sup>

Within the past three years the “placebo” needle has been developed. Such a device aims for credible simulation of needle penetration with minimal sensory stimulus. Rather like a stage dagger, the shaft of the placebo needle disappears into its own handle as the blunted tip presses on to the skin at the site of simulated insertion. The remaining challenge is in supporting the needle if it is to be left in place for any length of time. The first randomised controlled trial to use such a device yielded positive results for acupuncture in the treatment of supraspinatus tendonitis.<sup>4</sup> Further trials with a similar type of needle are underway at the department of complementary medicine in Exeter University.

In the light of these methodological developments, the suggestion from Irnich et al that acupuncture is likely to be more effective in the myofascial pain syndrome, and the considerable empirical support for this suggestion, we can be confident that future studies of sufficient size will determine whether or not the acupuncture needle has efficacy beyond placebo. Musculoskeletal pain has such an important impact on the community<sup>5</sup> that we must find funding for large scale, methodologically sound trials of this simple, relatively safe, and potentially efficacious technique.

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