CRITICAL REVIEW OF THE USE OF ACUPUNCTURE FOR THE MANAGEMENT OF CHRONIC ORTHOPEDIC PAIN

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INTRODUCTION

This paper is a review of studies regarding the use of acupuncture to effectively manage chronic pain stemming from orthopedic conditions. The five studies reviewed in this article range in year from 2002 to 2013. Although acupuncture is widely known for its ability to relieve and in some cases cure chronic pain from orthopedic issues, there have not been many convincing studies on the subject until somewhat recently. These five studies involve chronic pain in the most common areas, low back, shoulder, and neck. One of the studies also addresses the need for individualized over standardized care in the management of low back pain. The aim of this review is to show whether or not acupuncture is an effective modality for treating chronic orthopedic pain, and to begin to explore whether or not an individualized versus standardized mode of care is necessary. Results show that most studies are being conducted by qualified acupuncture personnel, although in two studies [2, 4] the training seemed a bit minimal. All studies were well designed, would be easy to repeat the intervention and the outcome measurements. Two of the studies [1, 2] used sham acupuncture, two of the studies [4,5] used acupuncture versus no acupuncture, and the study [3] regarding individual versus standardized care used a case by case selection of points versus a standard set of points given in the study. All of the studies [1, 2, 4, 5] regarding whether or not pain was effectively managed by acupuncture showed that this was indeed the case, while the study [3] regarding whether or not individual care was better than standardized care showed no significant difference between the two. Thus, this suggests that not only is acupuncture effective at managing chronic pain from orthopedic conditions, but that it may be possible to train people quickly to process large amounts of chronic orthopedic pain patients.

Acupuncture for orthopedic pain usually consists of a group of needles in the immediate location i.e. local, and a few points usually located on the limbs i.e. distal. Local points usually act on the area in pain by causing a variety of actions; release of tight muscle groups, micro-trauma to the area causing accumulation of blood cells and wound healing factors, and/or by causing a local analgesic effect. Distal points may act by a variety of means, some known and some unknown. However, here it is sufficient to say that through an extensive period of trial and error, ancient Chinese physicians have discovered that certain points have effects in other seemingly unrelated areas of the body.

Usually the treatment of acute pain, such as that due to injury, is a straight forward process and may not take very long to treat before the pain is reduced to a manageable level. However, managing

chronic pain with acupuncture is usually a longer process, sometimes taking from months to years depending on severity and chronicity. However, when the alternative is surgery and/or pain medications which may be expensive, carry significant side effects, and/or require the patient to be on them for the rest of their lives, acupuncture is a cheaper, safer, and easier alternative.

Needles may be inserted at a variety of depths, depending on location. When considering needling depth or point location, classically trained acupuncturists will use a measurement called a *cun,* which may defined as the width of the carpometacarpal joint of the patient's thumb. Normally, locally placed needles may be inserted anywhere from 0.5 to 3 cun, depending on the point and the patients build. Distal points may usually be needled anywhere from 0.1 to 1.5 cun, usually shallower on the hands and feet, and deeper in the arms and legs.

METHODS

In this review, articles were initially searched for using the Hawaii state public library system's journal browser. The Alternative HealthWatch search engine was used within the list of various journal browsers available to Hawaii state public library members. The five clinical trials on the management of chronic orthopedic related pain were dated from one in 2002 to two in 2013 and consisted of the following journals: Pain [1, 2, 4], Evidence Based Complementary Alternative Medicine [3], and Journal of Alternative Complementary Medicine [5]. Inclusion criteria included studies having to do with pain due to chronic orthopedic conditions, randomized clinical trials, a number of participants greater than or equal to 100, and demographic data for the study population. Exclusion criteria included pain due to sources other than orthopedic issues, no follow up data, no separate control and intervention groups, and no explanation of the educational background of the acupuncture practitioner.

Articles were initially reviewed using two diagnostic approaches for determining the quality of the studies having to do with acupuncture. The first of which is the Criteria for Learning to Evaluate Acupuncture Research (CLEAR), developed by Dr. Richard Hammerschlag at the Oregon College of Oriental Medicine (Hammerschlag, 2007). This highlights the experience of the acupuncturist(s) involved in the study, the randomization of patients into control and intervention groups, the blinding of medical staff and patients, and the repeatability of the clinical trial. The second guideline used is the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) which mostly assesses the

quality of the reporting of areas such as point selection rationale, all aspects of needling, treatment regiment, other methods of intervention, practitioner background, and control group methods.

REVIEW STUDIES ARTICLES 1-5

Study Article # 1

Guerra de Hoyos JA, Andrés Martín Mdel C, Bassas y Baena de Leon E, Vigára Lopez M, Molina López T, Verdugo Morilla FA, González Moreno MJ. (2004). Randomised trial of long term effect of acupuncture for shoulder pain. Pain. 2004 Dec;112(3):289-98.		
Questions	**Description**	**Answer to Question**
Were the training and clinical experience of the acupuncturist(s) stated?	Patients received a real acupuncture or placebo session every week, for 8 weeks, by two licensed (three years long title on Chinese acupuncture) acupuncturists; both with more than four years of experience in a primary care pain program with acupuncture and moxibustion techniques. Both acupuncturists have treated several thousand cases of shoulder pain patients and written a 201 case series several congress communications.	Yes
Were inclusion and exclusion criteria for patient selection presented?	Inclusion criteria were diagnosis (history, examination, Rx) of shoulder soft tissues lesions such as cuff tendonitis, capsulitis, bicipital tendonitis, bursitis with shoulder pain plus decreased movement (active, passive, counter resistance), local tenderness, and no swelling signs (local heat, redness); no recent shoulder trauma (previous 3 months); no previous acupuncture treatments; age of 18 or older, without upper limit but patient able to come to clinic for evaluation and treatment by his own means. Exclusion criteria were critical physical or mental condition, febrile condition, systemic dermatological conditions, neoplasms, allergy to diclofenac, referred pain from neck or thorax, rupture of tendons or bone fractures, pregnancy, litigation, no intention to participate or follow instructions.	Yes

Were patients assigned to the treatment group and the control or comparison group by a process described as randomized?	Participants were randomly allocated to acupuncture or placebo group. Randomization was performed using computer software (Sigesmuw) without stratification or blocking procedure, via a telephone call from the independent evaluator to the external centralized office. The allocation group was revealed only to the treating acupuncturist, who had no knowledge of diagnoses or other data evaluations.	Yes
Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups?	During first evaluation the following data were recorded: demographic data (age, sex, marital status, education level, working status, habits, physical exercise), clinical data (concurrent condition, shoulder pain diagnosis, pain location, duration of symptoms, repetitive strain injury or previous trauma), credibility (measured by Borkovek-Nau scale), quality of life (measured by Coop Wonca Charts), pain intensity (measured by visual analogue scale (VAS) and by Lattinen index), range of arm abduction (goniometer), and disability (measured by Shoulder pain and disability index, SPADI).	Yes, it is presented in a table in the data section of this paper
Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters?	The rationale for elected real acupuncture treatment was based on Chinese medicine (Bi Syndrome, channels involved, local and distant points election) and experience points Wang (Wang et al., 1990), but we used the same four points for every patient to standardize treatment making for easier statistical analysis and enabling the acupuncturist to apply treatment without knowing symptoms or diagnosis, 2 local points on the affected shoulder and 2 distant points in the opposite leg.	Yes

Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them?	Every patient was given 21 diclofenac pills for the next week's treatment (50 mg per pill) with instruction to take one of them every 8 h, if needed, for shoulder pain. Also every patient received famotidine pills (20 mg per pills) and the instruction to take one of them every 12 h, if needed, for dyspepsia. Patients were instructed to return for acupuncturist intervention and evaluator assessment of outcomes. After initial assessment an appointment for next day was given to the patient to start acupuncture treatment. For this study we used a special type of placebo needle; an adhesive ring with a cone, having a central hole (that cannot be seen when attached to skin), that allows the passage of a blunt tip needle of 1.5 cun (Chinese anatomical inch), whose shaft telescopes into the handle without penetrating skin. By this procedure the patient can only perceive a feeling of pressure. The patients included in both groups had no previous experience with acupuncture treatment. For real acupuncture treatment we used a sharp tip needle of 1.5 cun to penetrate the skin. In both cases the same length of needle handle could be seen outside the cone which keeps the needle in place. The needles were connected to an electro-acupuncture device with a led indicator to increase procedure credibility. The placebo group received a dummy stimulation, without current intensity. For the real acupuncture group the electrical device was set to 5–10 Hz and intensity to elicit light	Yes

	muscular twitching. The placebo procedure used is similar to other validated and published procedures. Patients received a real acupuncture or placebo session every week, for 8 weeks, by two licensed (three years long title on Chinese acupuncture) acupuncturists both with more than four years of experience in a primary care pain program with acupuncture and moxibustion techniques. Depth of needle insertion was 1 cun for all the locations. The acupuncturist first inserted leg needles elicited Deqi and connected terminal wires of the electroacupuncture device asking the patient to elevate the arm several times with the elbow extended as much as possible for 2–3 min. After that acupuncturist inserted shoulder needles and connected them to the electro-acupuncture device. All the needles were retained for 15 min and were stimulated during retention time with dense disperse waves of 5–10 Hz at sufficient intensity to elicit light muscular twitching. For placebo-acupuncture we followed the same procedure, but with the difference that a blunt needle was used, so it did not penetrate the skin, and the electrical device gave dummy stimulation to the needles. Both groups were treated in the same manner by the acupuncturist (except for placebo or real acupuncture depending on allocation group, which he knew via a telephone call) who tried not to give or receive any information to, or from, the patients, he applied the fixed set of points without having or making any diagnosis or evaluation. We used Chinese made filiform needles (Hao type), 0.32 gauge.	

	Blunt tip 1.5 cun length with telescopic handle, and sharp point 1.5 cun length, imported by Hispasia S.S. C/Virgen de Aguas Santas 8 41011 Sevilla and Electronic Acupuntoscope Model WQ-6F, manufactured at Beijing.	
Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study?	The primary outcome variable was the difference between groups in pain intensity measured by visual analogue scale (VAS), a widely validated numerical scale. Secondary variables were differences between groups in: pain measured by Lattinen Index, an index scale for pain intensity, easier to understand by patients with low socio-cultural level; range of movement (ROM) measured with a goniometer attached to arm and thorax, asking patient maximal arm abduction; number of pills consumed every week; change from baseline on SPADI global numerical score; pain and disability subscales scores (SPADI used visual analogue scales to rate 13 items related to shoulder-specific pain with five items and disability with 8 items, rating each item from 0 to 10, with 10 indicating the greatest pain or disability); credibility score before and after intervention; quality of life score measured with COOP/WONCA charts, an instrument that consists of six charts that measures six core aspects of functional status: physical fitness, feelings, daily activities, social activities, change in health and overall health. Each chart consists of a simple title, a question referring to the status of the patient and an ordinal five-point response scale illustrated with a simple drawing.	Yes, all of the outcome measures they used have been published in other papers

	Each item is rated on this five-point ordinal scale ranging from 1 ('no limitation at all') to 5 ('severely limited'); for 'change in health' score 1 means 'much better' and score 5 'much worse'. Global score reflects functional capacity, from 6 (no limitation at all) to 30 (severely limited); final global satisfaction with treatment measured with a numerical scale from no satisfaction at all (0) to maximal satisfaction (10). Assessment was always made the day before a treatment session. We did not separate control group from intervention group patients so as not to disclose an allocation sequence to the observer. We also registered general variables (age, gender, socio-cultural level, working status, previous trauma, litigation) that could affect outcomes.	
Was the assessor of treatment effectiveness described as blinded?	Evaluation during the follow-up period, and drug treatment recommendations, were performed in different places and times and by different evaluators, who had no knowledge of the type of acupuncture (real or placebo) applied to the patient.	Yes
Were patients asked to validate the placebo/sham control treatment?	No	No
Was follow-up data presented?	After evaluating and treating patients for seven weeks, independent evaluators performed two other evaluations at 3 and 6 months from the beginning, to test the maintenance of effects after finishing treatment. In addition, in the last visit (sixth month) they recorded credibility, quality of life and final global patient satisfaction with the treatment.	Yes
Was the Acupuncture used in addition to other type of therapy?	Every patient was given 21 diclofenac pills for the next week's treatment (50 mg per pill) with instruction to take one of them every 8 h, if needed, for shoulder pain. Also every patient received famotidine pills (20 mg per pills) and the instruction to take one of them	Yes

	every 12 h, if needed, for dyspepsia. In both cases the same length of needle handle could be seen outside the cone which keeps the needle in place. The needles were connected to an electro-acupuncture device with a led indicator to increase procedure credibility. The placebo group received a dummy stimulation, without current intensity. For the real acupuncture group the electrical device was set to 5–10 Hz and intensity to elicit light muscular twitching. The placebo procedure used is similar to other validated and published procedures.	
Do I agree with the study outcomes?	After intervention the acupuncture group showed a significantly greater improvement in pain than placebo group, measured as difference in VAS after seven weeks of starting treatment In the primary analysis pain score was significantly lower in the acupuncture group The score fell by 43% in the acupuncture group compared with 20% in controls (P<0.001). This result was robust to secondary analysis including imputed missing data (difference between groups of 1.34, P<0.001). The effect was already shown at the sixth week and was maintained up to 3 months and 6 months after starting treatment. Again these results were robust to secondary analysis including imputed missing data (difference between groups of 1.5 P<0.0005 at 3 months; 2.0, P<0.0005 at 6 months). There were also differences between groups in pain measured by Lattinen Index.	Yes

	In the same way, the acupuncture group experienced a significant improvement in pain and disability measured by SPADI scale as global score. Differences were already statistically significant at the first week after starting treatment. The acupuncture group showed a significantly greater improvement in range of motion at seven weeks of treatment . Again effect was maintained up to six months. The acupuncture group showed a significantly lower consumption of diclofenac from the first session up to seven weeks of treatment. Again effect was maintained up to six months: an average of 3 tablets/week in the acupuncture group versus 8 tablets/week in the placebo group. Credibility and quality of life were measured at entry before placebo or acupuncture intervention and at final visit (six months). The acupuncture group showed a significantly higher change in credibility (12%, P<0.001). In placebo group the change was 4%. Quality of life improvement was also greater with active treatment: about a 5.3% for placebo and 20% for the acupuncture group. At final visit, at six months, final satisfaction was similar in both groups: 8.9 (SD, 1.1) for the placebo and 9.3 (SD, 1.0) for the acupuncture group.	

Checklist of STRICTA items for the above (Study Article # 1).

Intervention	Description of Item	Answer
1) Acupuncture rationale	1a) Style of acupuncture	No
	1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points)	Yes
	1c) Literature sources to justify rationale	Yes
2) Needling details	2a) Points used (uni/bilateral)	Yes
	2b) Numbers of needles inserted	Yes
	2c) Depths of insertion (e.g. *cun* or tissue level)	Yes
	2d) Responses elicited (e.g. *de qi* or twitch response)	Yes
	2e) Needle stimulation (e.g. manual or electrical)	Yes
	2f) Needle retention time	Yes
	2g) Needle type (gauge, length, and manufacturer)	Yes
3) Treatment regimen	3a) Number of treatment sessions	Yes
	3b) Frequency of treatment	Yes
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	Yes
5) Practitioner background	5a) Duration of relevant training	Yes
	5b) Length of clinical experience	Yes
	5c) Expertise in specific condition	No
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert)	Yes
	6b) Explanations given to patients of treatment and control interventions	No
	6c) Details of control intervention (precise description, as for Item 2 above, and other items if different)	Yes
	6d) Sources that justify choice of control	Yes

Study # 1 showed a significantly greater improvement in pain in the intervention group than in the sham acupuncture group as measured by VAS (visual analogue scale), Lattinen Index, and SPADI (shoulder pain and disability index) scale. In addition to this, the intervention group also showed a greater improvement in range of motion and a lowered use of diclofenac (NSAID). All of these metrics were maintained when measured again after the treatments stopped at a six month follow up.

Study Article # 2

Molsberger AF, Mau J, Pawelec DB, Winkler J. (2002). Does acupuncture improve the orthopedic management of chronic low back pain--a randomized, blinded, controlled trial with 3 months follow up. Pain. 2002 Oct;99(3):579-87.		
Questions	**Description**	**Answer to Question**
Were the training and clinical experience of the acupuncturist(s) stated?	The acupuncture therapy was carried out by an experienced medical doctor, who had studied acupuncture in China (Beijing).	Yes
Were inclusion and exclusion criteria for patient selection presented?	Inclusion criteria: low back pain (LBP), that is pain between the 12th rib and the gluteal fold; with pain for 6 weeks or longer; with an average pain score of 50 mm or more on a 100 mm visual analogue scale (VAS) during the last week, age between 20 and 60 years; the ability to communicate in German; Exclusion criteria: no sciatica or other neurological disorders; no history of disc or spine surgery; no systemic bone and joint disorders (e.g. rheumatoid arthritis); no previous treatment with acupuncture; no overt psychiatric illness; no pregnancy; not dependent on regular intake of analgesics; no incapacity for work longer than 6 months preceding the trial and not currently awaiting decision on an application for pension or disability benefits (the latter to exclude a conflict of interest between the expected social benefit payments and possible positive treatment effects).	Yes
Were patients assigned to the treatment group and the control or comparison group by a process described as randomized?	According to a computer generated randomization list of admitted patients were randomly assigned to either of three groups: Verum + COT, Sham + COT, nil + COT. Central telephone randomization was provided by the Department of Statistics in Medicine, Heinrich Heine University, Dusseldorf. Randomization was stratified into four balanced strata according to the length of pain history: less than 0.5 years (stratum 1), 0.5–2.0	Yes

	years (stratum 2), 2.0–5.0 years (stratum 3), and more than 5.0 years (stratum 4).	
Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups?	Due to the reorganization of the public health system in Germany, the rehabilitation clinic was closed 1.5 years after the beginning of the trial and the trial had to be stopped. At that time 186 patients were enrolled in the trial and had completed the treatment protocol. The intention to treat (ITT) analysis comprises all 186 patients as randomized, irrespective of their consistency with their compliance or adherence to the protocol specifications to either Verum + COT (65), Sham + COT (61), or nil + COT (60). The per-protocol population (PPP, n ¼ 174) analysis excluded 12 patients, who did not meet the protocol population criteria; group sizes then were Verum + COT (58), Sham + COT (58), nil + COT (58). The numbers of patients per stratum (ITT) were: stratum 1-pain history less than 0.5 year, n ¼ 6; stratum 2–0.5–2.0 years, n ¼ 27; stratum 3–2.0–5.0 years, n ¼ 40; stratum four more than 5.0 years, n ¼ 113. No patient had a pain history shorter than 3 months. In the trial population (97 men, 89 women) the typical patient was approximately 50 years old, reported a moderate to severe pain (VAS score 66), with an average duration of LBP of 9.9 years.	Yes

	Baseline characteristics (gender, age, duration of LBP, finger-to-ground distance, Schober's sign, intensity and frequency of pain, night pain and experience in and attitude toward acupuncture, number of days in hospital) were similar across the three treatment groups.	
Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters?	After a literature review on acupuncture for LBP only widely accepted acupuncture points were selected (Beijing College of Chinese Medicine, 1987; Stux and Pomeranz, 1998; Xinnong, 1987). Standard points in the lumbar region (adjacent points) were urinary bladder 23, 25, and gallbladder 30; standard points on the lower extremity (distal points) were urinary bladder 40, 60 and gallbladder 34. Additionally up to four points of maximum pain 'Ahshi points' (locus dolendi, trigger points), which were often close but not necessarily identical to Bl 54, 31, 32 were needled.	Yes
Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them?	Patients were blinded against verum and sham acupuncture treatment, but not against standard therapy. According to randomization, all enrolled patients of the rehabilitation hospital received one of the following treatments. (a) nil + COT (conventional orthopedic therapy exclusively).These patients received the conventional conservative orthopedic treatment only. On a standardized, daily basis they received physiotherapy, physical exercise, back school, mud packs, and infrared heat therapy. On demand they received 50 mg diclofenac up to three times a day. Injections or cortisone application of any kind were not allowed. Other than that, information and handling of these patients was identical to those of the other two groups.	Yes

	(b) Verum 1 COT (verum acupuncture and conventional orthopedic therapy). In addition to the conventional conservative orthopedic therapy all patients received 12 verum acupuncture treatments, three per week, each lasting for 30 min. The acupuncture therapy was carried out by an experienced medical doctor, who had studied acupuncture in China (Beijing). After a literature review on acupuncture for LBP only widely accepted acupuncture points were selected. Standard points in the lumbar region (adjacent points) were urinary bladder 23, 25, and gallbladder 30; standard points on the lower extremity (distal points) were urinary bladder 40, 60 and gallbladder 34. Additionally up to four points of maximum pain 'Ahshi points' (locus dolendi, trigger points), which were often close but not necessarily identical to Bl 54, 31, 32 were needled. Depending on the site of the needle and the type of pain reported by the patient, needle insertion ranged from 1 to 10 cm and needle manipulation was mild to strong. Always a numb, warm feeling around the acupuncture point (Deqi) was achieved. During the acupuncture treatment, no additional treatment was administered. (c) Sham 1 COT (sham acupuncture and conservative orthopedic therapy). In addition to the daily conservative orthopedic therapy, all patients received 12 sham acupuncture treatments, three per week, each lasting for 30 min. Sham acupuncture was standardized to ten needles applied superficially (depth of needle insertion was less than 1 cm) at defined non-acupuncture points of the lumbar region, and five needles on either side of the back. Other than the application of sham acupuncture, information and handling of these patients was identical to those of the verum group.	

Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study?	Directly after the end of the 4 week in-house treatment protocol, all patients-with the help of the independent examiner, evaluated their pain intensity on a VAS (referring to the average pain level during the last 7 days) and rated the effectiveness of the treatment protocol from 'excellent, good, satisfactory to failed' on a four-point box scale (4-PBS). Schober's sign and the finger-to-ground distance were measured, too. Follow up data were measured 3 months after the end of the treatment protocol. Data were taken in the same way as directly after treatment, but at that time on an outpatient basis by the patient's family doctor, who had not been informed about the assigned treatment group. The independent examiner in the clinic and the family doctor were blinded against verum and sham acupuncture (blinded observer) but not against conservative orthopedic treatment alone (nil + COT).	Yes
Was the assessor of treatment effectiveness described as blinded?	The independent examiner in the clinic and the family doctor were blinded against verum and sham acupuncture (blinded observer) but not against conservative orthopedic treatment alone (nil + COT).	Yes, but only for the two treatment groups receiving either the real or sham acupuncture, not those receiving no acupuncture
Were patients asked to validate the placebo/sham control treatment?	No	No
Was follow-up data presented?	Follow up data were measured 3 months after the end of the treatment protocol. Data were taken in the same way as directly after treatment, but at that time on an outpatient basis by the patient's family doctor, who had not been informed about the assigned treatment group.	Yes

Was the Acupuncture used in addition to other type of therapy?	Conventional conservative orthopedic treatment consisted of a standardized, daily basis they received physiotherapy, physical exercise, back school, mud packs, infrared heat therapy. On demand they received 50 mg diclofenac up to three times a day. Injections or cortisone application of any kind were not allowed.	Yes
Do I agree with the study outcomes?	The following analyses include all patients and are on intention to treat The patient PPP analyses do not differ significantly. Mean VAS scores The mean VAS scores changed (i) in the Verum + COT group from baseline 68 to 26 directly after treatment and to 23 after 3 months; (ii) in the Sham + COT group from baseline 64 to 36 directly after treatment and to 43 after 3 months; (iii) in the nil + COT group from baseline 67 to 39 directly after treatment and to 52 after 3 months. Pain relief after 3 months After 3 months, a pain relief of at least 50% was reported by 77% (95%CI 62–88%) in the Verum + COT group (n = 47), 29% (95%CI 16–46%) in the Sham + COT group (n = 41), 14% (95%CI 4–30%) in the nil + COT group (n = 36). Results are significant for Verum + COT versus Sham + COT ($P < 0.00003$) and for Verum + COT versus nil + COT ($P < 0.00001$) after appropriate adjustments for multiple testing Pain relief on VAS directly after treatment protocol A pain relief of at least 50% was reported by: 65% (95%CI 51–77%) in the Verum + COT	Yes

	group (n = 60), 34% (95%CI 22–49%) in the Sham + COT group (n = 58), 43% (95%CI 29–58%) in the nil + COT group (n = 53). Results are significant for Verum + COT versus Sham + COT (P = 0.013) and are not statistically significant for Verum + COT versus nil + COT (P > 0.05) after appropriate adjustments for multiple testing. Treatment effect on 4-PBS directly after treatment An excellent or good effect was reported by: 84% (95%CI 72–92%) in the Verum + COT group (n = 62), 67% (95%CI 54–79%) in the Sham + COT group (n = 61), 56% (95%CI 42–70%) in the nil + COT group (n = 55). Results are significant for Verum + COT versus nil + COT (P < 0.016) and are not statistically significant for Verum + COT versus Sham + COT (P > 0.05) after appropriate adjustments for multiple testing. Treatment effect on 4-PBS after 3 months An excellent or good improvement was reported by: 73% (95%CI 58–85%) in the Verum + COT group (n = 49), 55% (95%CI 38–70%) in the Sham + COT group (n = 42), 30% (95%CI 15–47%) in the nil + COT group (n = 37). Results are statistically significant for Verum + COT versus nil + COT (P < 0.0006) and are not significant for Verum + COT versus Sham + COT (P > 0.05) after appropriate adjustments for multiple testing. Analysis of end points only for patients with a pain history of at least 6 months. Significant and not-significant results do not change when patients with a LBP pain history of less than 6 months (stratum 1, n = 6) are excluded from analysis	

	Schober's sign, finger to ground distance and diclofenac intake In the values of Schober's sign, finger-to-ground distance and diclofenac intake no significant changes were found. Before treatment 18% patients of the Verum + COT group took diclofenac versus 20% of the Sham + COT and 15% of the nil + COT group. After end of treatment protocol patients diclofenac intake decreased/stayed stable/increased in: Verum + COT, 11%/82%/7%; Sham + COT, 7%/84%/9%; and nil + COT, 11%/75%/14%. After 3 months patients diclofenac intake decreased/stayed stable/increased in: Verum + COT, 7%/82%/11%; Sham + COT, 10%/80%/10%; and nil + COT, 9%/68%/23%. No important adverse events or side effects in either of the intervention groups were observed. Handling of missing data After 3 months data could be obtained from 124 (67%) patients of an ITT population of 186 randomized patients. In accordance with the guidelines of the EMEA in a second analysis we counted all patients missing after 3 months as failures (worst case assumption) or as successes (best case assumption, EMEA, 2001). Results of Verum + COT versus Sham + COT and Verum + COT versus nil + COT remain statistically significant in the worst-case (adjusted $P < 0.0001$, $P < 0.00000002$) and best case analysis (adjusted $P < 0.000528$, $P < 0.00011$).	

	For statistical reasons, we also performed a mixed worst/best case assumption analysis where all patients were considered as failures when missing in Verum + COT, and as successes when missing in either Sham 1 COT or nil 1 COT which lead to no statistically significant differences. This is the least favorable assumption for Verum + COT regarding missing values.	

Checklist of STRICTA items for the above (Study Article # 2).

Intervention	**Description of Item**	**Answer**
1) Acupuncture rationale	1a) Style of acupuncture 1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) 1c) Literature sources to justify rationale	No Yes Yes
2) Needling details	2a) Points used (uni/bilateral) 2b) Numbers of needles inserted 2c) Depths of insertion (e.g. *cun* or tissue level) 2d) Responses elicited (e.g. *de qi* or twitch response) 2e) Needle stimulation (e.g. manual or electrical) 2f) Needle retention time 2g) Needle type (gauge, length, and manufacturer)	Yes Yes Yes Yes Yes Yes No
3) Treatment regimen	3a) Number of treatment sessions 3b) Frequency of treatment	Yes Yes
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	Yes
5) Practitioner background	5a) Duration of relevant training 5b) Length of clinical experience 5c) Expertise in specific condition	No No No
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) 6b) Explanations given to patients of treatment and control interventions 6c) Details of control intervention (precise description, as for Item 2 above, and other items if different) 6d) Sources that justify choice of control	Yes No Yes No

Study #2 showed a significant decrease in VAS, a similar decrease pain of 50% or more, and a similar improvement on a 4-PBS (four point box scale) in the acupuncture and sham groups when combined with standard orthopedic treatment immediately following the end of treatment. However, none of these were maintained in the sham group when measured again 3 months post treatment.

Study Article # 3

Pach D, Yang-Strobel X, Lüdtke R, Roll S, Icke K, Brinkhaus B, Witt CM. (2013). Standardized versus Individualized Acupuncture for Chronic Low Back Pain: A Randomized Controlled Trial. Evid Based Complement Alternat Med. 2013;2013:125937.		
Questions	**Description**	**Answer to Question**
Were the training and clinical experience of the acupuncturist(s) stated?	Chinese-born medical doctor trained in western and Chinese medicine. The MD usually provides both conventional care and acupuncture to her patients. Has 25 years of clinical MD practice and trained in Chinese medicine with 20 years' experience in treating low back pain with acupuncture.	Yes
Were inclusion and exclusion criteria for patient selection presented?	inclusion criteria: age of at least 18 years, male or female, low back pain for at least 3 months (clinical diagnosis of chronic low back pain confirmed by a medical specialist) and indication for treatment of low back pain with acupuncture confirmed by a medical specialist, average pain intensity of the last 7 days more or equal to 40mmmeasured by a visual analogue scale (VAS 0–100 mm), intellectual and physical ability to participate in the study, and informed consent. Main exclusion criteria were acupuncture during the last 6 months, start of a new therapy for low back pain within the last 4 weeks, pregnancy, substance or drug abuse, and participation in another clinical trial.	Yes

Were patients assigned to the treatment group and the control or comparison group by a process described as randomized?	The randomization sequence was generated by a data manager, who was not involved in the analysis of the data and enrolment of the patients, with Microsoft Office Excel 2003 in a 1:1 ratio stratified for gender. The list was integrated into a secured database (Microsoft Office Access 2003) and was not accessible to the other staff members or the study physician. Randomization took place in the practice using the secured database. The patient's allocation to the different treatment groups and the patient identification number for each single patient was assigned and accessible for the enrolling physician after patient data such as name and date of birth was entered and saved in the secured database. With that approach, the randomization list was hidden in the database and not accessible for anyone participating in the enrollment.	Yes
Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups?	Patients were recruited from the regular patients of a general medicine practice in Berlin, Germany, run by a Chinese-born medical doctor trained in western and Chinese medicine. From 163 possible participants screened, 150 were enrolled between January 2009 and January 2011 and randomized into the two groups (standardized group n = 78, individualized group n = 72). The mean age was 57.8 ± 12.5 (mean ± sd) years, 58% were female and the mean duration of symptoms was 16.3 ± 12.3 years. At baseline, the average pain intensity on the VAS was 58.5±11.3 mm Six patients were lost to follow up at week eight but were included in the ITT analysis.	Yes

Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters?	Individualized acupuncture was based on syndrome diagnosis, which was done before each treatment session. The standardized acupuncture was based on the acupuncture intervention from a large multicenter trial previously performed by our group, developed by a large and systematic expert consensus. From this trial's database, we determined the most frequently used points. Two Chinese medicine experts with more than 15 years of experience in acupuncture finalized the standardized treatment protocol used for the present study.	Yes
Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them?	All patients received Chinese medicine diagnostics including examination of pulse and tongue to avoid a bias due to a possible placebo effect caused by this kind of examination. Both acupuncture interventions were applied by the same medical doctor specialized in western general medicine (25 years of clinical practice) and trained in Chinese medicine with 20 years' experience in treating low back pain with acupuncture. In our study, two treatment sessions per week had to be applied, with a maximum number of 10 to 15 sessions depending on the patient's individual needs. Only body-needle acupuncture without electrical stimulation was allowed. Standardized acupuncture used the following points: (1) local points Bl 23, 24, and 25 and (2) distant points Bl 40, Bl 60, Gb 34, and K 3 in each session on both sides of the body. Individualized acupuncture was based on syndrome diagnosis, which was done before each treatment session. However, not more than 14 needles were applied to be comparable with the group with standardized acupuncture.	Yes

	For this study, we purchased Viva Sterile Acupuncture Needles, for single use only, pyrogen free, from Oxford Medical Supplies Ltd., Fairford, Gloucestershire, England. They had a needle length of 20 to 40mm and a diameter of 0.2 to 0.3 mm. They were vertically inserted 1-2 cm deep into the skin depending on the size of the respective muscle. The needles were manually stimulated by rotation and lift-thrusting until a deqi sensation was reached. The needle retention time was about 25 min in both groups. Because it was a trial in a real-life setting, comedication was allowed in both groups, and their intake was documented using diaries.	
Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study?	The primary outcome measure was the area under the curve (AUC) summarizing the average low back pain intensity over eight weeks. For this, the back pain intensity of the last 24 hours was rated daily in a diary using a visual analogue scale [22] (VAS, 0–100 mm, 0 = no pain, 100 = worst imaginable pain) and then summed up over 56 days. Secondary outcome measures included the VAS for pain during the previous 7 days at eight and 26 weeks and the following outcomes at eight and 26 weeks: back function (Hannover Functional Ability Questionnaire, HFAQ; in German, Funktionsfragebogen Hannover Rucken), general health related quality of life (SF-36) [24], days absent from work, mean number of treatment sessions, mean duration of treatment, and days with physical therapy because of back pain. The patient diary (baseline to week 8) was also used to calculate the number of days with pain medication between weeks one and eight. In addition, we evaluated the safety of the interventions (recording of adverse events at each visit through the treatment physician) and blinding (patient guess of intervention group at 8 weeks).	Yes

	Except for safety data and data in the diary, outcome data was obtained by a study nurse who was not blinded to the treatment arm. To assess the patients' and doctor's expectation for improvement due to the treatment before randomization, patients and doctors had to document their expectation of the therapy on categorical scales: "recovery," "distinct improvement," "slight improvement," and "no improvement" as well as their assessment of the presumed therapy's effectiveness: "very effective," "effective," "small effect," and "no effect."	
Was the assessor of treatment effectiveness described as blinded?	Except for safety data and data in the diary, outcome data was obtained by a study nurse who was not blinded to the treatment arm.	No
Were patients asked to validate the placebo/sham control treatment?	After the end of treatment, patients were asked to guess what treatment intervention had been administered to them.	Yes
Was follow-up data presented?	Follow-up data after 26 weeks was available for 139 patients (standardized group n = 73, individualized group n = 66).	Yes
Was the Acupuncture used in addition to other type of therapy?	Because it was a trial in a real-life setting, co-medication was allowed in both groups, and their intake was documented using diaries.	
Do I agree with the study outcomes?	Both groups showed a clinically meaningful improvement after 8 weeks regarding pain severity. The primary endpoint, the area under the curve (AUC) for the pain severity from baseline to end of week 8, was comparable between both groups and showed no statistically significant differences (adjusted group difference, 285.8 (95% CI −33.9; 605.5); P = 0.080). Secondary outcomes showed consistent results. The average pain severity after 8 weeks and 26 weeks did not differ significantly between both groups. Accompanying therapy including concurrent therapies	Yes

	was not significantly different between both groups regarding days with medication intake (week 1 to end of week8), days with physical therapy because of back pain (week 1 to end of week 8), and number of therapy sessions and duration of therapy (baseline to end of therapy). Furthermore, for the secondary outcomes HFAQ, QoL, and sick leave days at week 8 and week 26, no significant group differences were observed. Of the 150 patients in both intervention groups, none reported acupuncture-related side effects. However, adverse events reported by the patients included breast cancer, herpes zoster, and common cold (individualized group: 7 events, standardized group: 8 events), but none had a causal relation to the acupuncture treatment. After the end of treatment, patients were asked to guess what treatment intervention had been administered to them. In the standardized group, 78.1% guessed they were in the standardized group while, in the individualized group, 55.7% guessed they were in the individualized group.	

Checklist of STRICTA items for the above (Study Article # 3).

Intervention	**Description of Item**	**Answer**
1) Acupuncture rationale	1a) Style of acupuncture 1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) 1c) Literature sources to justify rationale	Yes Yes Yes
2) Needling details	2a) Points used (uni/bilateral) 2b) Numbers of needles inserted 2c) Depths of insertion (e.g. *cun* or tissue level) 2d) Responses elicited (e.g. *de qi* or twitch response) 2e) Needle stimulation (e.g. manual or electrical) 2f) Needle retention time 2g) Needle type (gauge, length, and manufacturer)	Yes Yes Yes Yes Yes Yes Yes

3) Treatment regimen	3a) Number of treatment sessions 3b) Frequency of treatment	Yes Yes
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	Yes
5) Practitioner background	5a) Duration of relevant training 5b) Length of clinical experience 5c) Expertise in specific condition	Yes Yes Yes
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) 6b) Explanations given to patients of treatment and control interventions 6c) Details of control intervention (precise description, as for Item 2 above, and other items if different) 6d) Sources that justify choice of control	Yes Yes Yes Yes

Study #3 showed that there was no significant difference when treating chronic low back pain whether using individualized care using traditional Chinese medicine metrics or by using a selection of commonly used points for back pain from a previous study by the same group

Study Article # 4

Witt CM, Jena S, Brinkhaus B, Liecker B, Wegscheider K, Willich SN. (2006). Acupuncture for patients with chronic neck pain. Pain. 2006 Nov;125(1-2):98-106.		
Questions	**Description**	**Answer to Question**
Were the training and clinical experience of the acupuncturist(s) stated?	For participation in this study the physicians were required to hold at least an ‘‘A-diploma’’ based on 140 h certified acupuncture education. This education and other trainings include variations in style and technique of acupuncture.	Somewhat. Minimal training is listed, but not clinical experience
Were inclusion and exclusion criteria for patient selection presented?	For inclusion in this study, patients had to meet the following criteria: clinical diagnosis of chronic neck pain with a disease duration of more than six months; age P18 years; written informed consent. The exclusion criteria for patients were:	Yes

	protrusion or prolapse of one or more intervertebral discs with concurrent neurological symptoms; prior vertebral column surgery; infectious spondylopathy; neck pain caused by inflammatory, malignant, or autoimmune disease; congenital deformation of spine except slight lordosis or scoliosis; compression fracture caused by osteoporosis; spinal stenosis and spondylolysis or spondylolisthesis.	
Were patients assigned to the treatment group and the control or comparison group by a process described as randomized?	Patients who agreed to randomization were allocated to an acupuncture group that received immediate acupuncture treatment or to a control group that received delayed acupuncture treatment after three months. After giving informed consent, the subjects were randomized using a central telephone randomization procedure (in blocks of 10; random list generated with SAS). Patients who declined to be randomized were included in a third arm and also received immediate acupuncture treatment (non-randomized acupuncture group). 1880 were randomized to acupuncture and 1886 to control, and 10,395 included into the non-randomized acupuncture group	Yes, for the randomized group
Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups?	14,161 patients with chronic neck pain (duration >6 months) (mean age 50.9 ± 13.1 years, 68% female) Non-randomized patients had more severe symptoms at baseline and showed higher neck pain and disability improvement compared to randomized patients.	Yes
Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters?	The aim was to assess the effectiveness of acupuncture in general medical practice. Because of this each patient could be treated individually and the number of needles and the acupuncture points used were chosen at the physicians' discretion.	Yes

Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them?	Each patient in the randomized and non-randomized acupuncture group received up to 15 acupuncture sessions during the first three months and no acupuncture between three and six months. The aim was to assess the effectiveness of acupuncture in general medical practice. Because of this each patient could be treated individually and the number of needles and the acupuncture points used were chosen at the physicians' discretion. Only needle acupuncture (with disposable one-time needles and manual stimulation) was allowed, whereas other forms of acupuncture treatment (e.g. laser acupuncture, electro-acupuncture, moxibustion) were not permitted. The control group was not allowed to use any kind of acupuncture during the first three months. In all three treatment groups, the patients were allowed to use any additional conventional treatments as needed.	Mostly, although details about the points used and needles used were vague to non-existent
Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study?	The patients completed standardized questionnaires (including sociodemographic characteristics) at baseline and after three and six months (because of the high number of patients participating in the non-randomized acupuncture group a random sample of 50% received the questionnaire after six months). The primary outcome measure was neck pain and disability after three months as assessed by the validated neck pain and disability scale developed by Wheeler (Wheeler et al., 1999). The 20 items of this scale measure the intensity of pain, its interference with vocational, recreational, social, and functional aspects of living; and the presence and extent of associated factors (Wheeler et al., 1999). As secondary outcome we used the percent	Mostly, if we had access to their standardized questionnaire

	reduction of neck pain and disability since in all three groups reductions were roughly proportional to the baseline neck pain and disability. If the neck pain and disability increased for an individual patient during the follow-up, the percentage was calculated with respect to the maximum possible improvement and given a negative sign. Patients who showed an improvement of at least 20% for neck pain and disability were considered to be treatment responders. Further secondary outcome parameters included changes of the SF-36 (Bullinger and Kirchberger, 1998) component scales and its sub-scores to assess health-related quality of life. Side effects were evaluated using patient and physician questionnaires after three months. In order to study the maintenance of therapeutic success in the acupuncture groups and the effect of delayed acupuncture treatment in the control group, changes from baseline to six months were calculated analogously.	
Was the assessor of treatment effectiveness described as blinded?	No, it is unknown if the assessor of the patients knew which patients had received acupuncture or not	No
Were patients asked to validate the placebo/sham control treatment?	No	No
Was follow-up data presented?	The follow-up period per patient was three months, following an assessment after the initial active treatment phase at three months.	Yes
Was the Acupuncture used in addition to other type of therapy?	All subjects were allowed to receive usual medical care in addition to study treatment. Only needle acupuncture (with disposable one-time needles and manual stimulation) was allowed, whereas other forms of acupuncture	Only acupuncture and standard western medical treatment for these types of injuries

	treatment (e.g. laser acupuncture, electro-acupuncture, moxibustion) were not permitted.	
Do I agree with the study outcomes?	In the primary analysis after three months, neck pain and disability improvement was more pronounced in the acupuncture than in the control group (neck pain: by 16.2 (SE: 0.4) to 38.3 (SE: 0.4); and disability: by 3.9 (SE: 0.4) to 50.5 (SE: 0.4), difference 12.3 (95% confidence interval (CI): 11.3, 13.3), $p < 0.001$), after adjustment for baseline differences. In neck pain and disability and quality of life (on all SF-36 subscales and both component scores), the three-month improvement was significantly more pronounced in the acupuncture than in the control group. The comparison of the randomized and the non-randomized acupuncture groups after three months revealed that the acupuncture effect was more pronounced in non-randomized patients with regard to neck pain and disability, most SF-36 subscales (with exception of general health perception, vitality and role emotional) and both component scales According to the multivariate analysis consistently over all treatment groups and independent of treatment, reduction of neck pain and disability was significantly ($p < 0.001$) more pronounced with higher education, female gender, younger age, with higher baseline physical or mental quality of life and more pronounced neck pain and disability at baseline. Regardless of whether they received acupuncture or not, patients performed better when the routine proportion of acupuncture treatments of the total work of the physician was higher ($p < 0.001$). Also after adjusting for acupuncture experience neck pain reduction differed significantly	Yes

	between physicians ($p < 0.001$). Treatment responses were significantly more pronounced in the acupuncture patients not consenting to randomization than in the randomized acupuncture patients (difference adjusted for baseline variables 2.4% (0.9–3.9%) in favour of non-randomized patients, $p = 0.002$), i.e., the selection due to the randomization requirement could not be explained by the model. After adjustment, the additional percent reductions of neck pain due to randomized acupuncture were estimated to be 22.7% (20.7%, 24.6%), $p < 0.001$, and thus slightly less pronounced than the unadjusted estimates. However, only one acupuncture effect modifier could be identified: the acupuncture effects on neck pain and disability were more pronounced in women than in men (24.0% vs 19.8%, $p < 0.001$). The physician's acupuncture qualification (e.g. hours of training, years of experience) had no significant influence on the effect of the treatment. The three month successes were essentially maintained and only slightly reduced. In the randomized acupuncture group, the six-month responder rate was 56.2%. In the non-randomized group the responder rate was 55.0%. Following delayed acupuncture, control patients almost caught up with the patients randomized to immediate acupuncture therapy. However, immediate acupuncture was significantly superior to delayed acupuncture in reduction of neck pain and disability, physical functioning, bodily pain	

	reduction, in the mental SF-36 component and all SF-36 sub-scores and in the responder rate (54.5% vs 48.2%, $p < 0.001$).	

Checklist of STRICTA items for the above (Study Article # 4).

Intervention	**Description of Item**	**Answer**
1) Acupuncture rationale	1a) Style of acupuncture 1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) 1c) Literature sources to justify rationale	No No No
2) Needling details	2a) Points used (uni/bilateral) 2b) Numbers of needles inserted 2c) Depths of insertion (e.g. *cun* or tissue level) 2d) Responses elicited (e.g. *de qi* or twitch response) 2e) Needle stimulation (e.g. manual or electrical) 2f) Needle retention time 2g) Needle type (gauge, length, and manufacturer)	No No No No Yes No No
3) Treatment regimen	3a) Number of treatment sessions 3b) Frequency of treatment	Yes Yes
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	No
5) Practitioner background	5a) Duration of relevant training 5b) Length of clinical experience 5c) Expertise in specific condition	Yes No No
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) 6b) Explanations given to patients of treatment and control interventions 6c) Details of control intervention (precise description, as for Item 2 above, and other items if different) 6d) Sources that justify choice of control	No No No No

Study #4 showed the people receiving acupuncture along with standard western medical care had a more pronounced improvement (as measured by a validated neck pain and disability scale developed by Wheeler et al., 1999) in neck pain and disability three months post treatment. Quality of life scores

(physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, mental health) as measured by the SF-36 (short form 36) subscale also showed a significantly pronounced improvement in the intervention versus the control group at the end of the three month follow up.

Study Article # 5

Weiss J, Quante S, Xue F, Muche R, Reuss-Borst M. (2013). Effectiveness and acceptance of acupuncture in patients with chronic low back pain: results of a prospective, randomized, controlled trial. J Altern Complement Med. 2013 Dec;19(12):935-41.		
Questions	**Description**	**Answer to Question**
Were the training and clinical experience of the acupuncturist(s) stated?	Two Chinese physicians with education in Traditional Chinese Medicine	Yes
Were inclusion and exclusion criteria for patient selection presented?	Inclusion criteria were chronic low back pain with duration of at least 6 months and age 25–75 years. Exclusion criteria included contraindications to acupuncture, such as anticoagulation with phenprocoumon or warfarin; coagulation disorders or thrombocytopenia (platelet count < 150,000 cells/mm3); poor fluency in German language; insufficient adherence; recent surgical treatment; and herniated vertebral discs, either minor herniations of less than 6 months' duration or major herniations of any duration	Yes
Were patients assigned to the treatment group and the control or comparison group by a process described as randomized?	A total of 160 patients were randomly assigned to one of two treatment groups. Randomization was done by the Institute for Epidemiology and Medical Biometry of the University of Ulm, Germany, by using a balanced block randomization	Yes

Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups?	Patients with chronic low back pain in their own inpatient rehabilitation program. 67% men and 33% women with a mean age of 50.7	Yes
Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters?	Diagnosis and treatment accorded with TCM principles, with a focus on medical history, tongue, and pulse diagnosis. Fixed positions of the needles were not mandated so that the therapists were not restricted in their treatment options. Each patient was treated individually according to the opinion of the TCM physician.	Yes, the rational was to allow the TCM doctors to do what they believed was best for each patient on a case by case basis
Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them?	All patients participated in a standardized 21-day inpatient rehabilitation program according to current German guidelines. Patients in the intervention group additionally received acupuncture twice weekly on a fixed schedule. Acupuncture was done by two Chinese physicians, who had completed education in TCM in China and had practiced in Germany for several years. Diagnosis and treatment accorded with TCM principles, with a focus on medical history, tongue, and pulse diagnosis. Fixed positions of the needles were not mandated so that the therapists were not restricted in their treatment options. Each patient was treated individually according to the opinion of the TCM physician. Acupuncture was done with two different types of sterile disposable needles: VQ-3210 (0.25 · 25mm) and VQ-3205 (0.25 · 13 mm). The duration of each session varied between 30 and 40 minutes. Tui na massage and a magnet lamp (TDP-lamp CQ-35, Chongqing Xinfeng Medical Instruments Co. Ltd., Chongqing, China) were additionally used at the discretion of the TCM physicians. Patients were advised to rest for 30 minutes after acupuncture.	Mostly, but the diagnoses reported and points used are not given

Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study?	At the beginning and end of the rehabilitation program, as well as 3 months after rehabilitation, patients completed questionnaires about health-related quality of life (SF-36), sociodemographic and clinical data, attitude towards TCM (including acupuncture), pain (quality, intensity, duration), and adverse events. The SF-36 is a validated questionnaire with 36 items that assess physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. Sociodemographic and clinical data, attitude towards TCM, quality, intensity and duration of pain, and adverse events were determined by using questionnaires developed by the research team. The questionnaire on pain was completed by the patients themselves to describe how often in the previous week they had back pain while sitting/standing, walking, or bearing moderate (<= 5 kg) or heavy (>= 10 kg) weight. Additionally, patients were asked to report the frequency of prickling in hands or feet as ‘‘never,’’ ‘‘sometimes,’’ ‘‘every day,’’ ‘‘several times a day,’’ or ‘‘constantly.’’ Patients also reported the duration of painful episodes.	Mostly. The questionnaires developed by the research team were not given in the paper
Was the assessor of treatment effectiveness described as blinded?	Assessors were the researchers in most cases.	No
Were patients asked to validate the placebo/sham control treatment?	No	No
Was follow-up data presented?	At the beginning (t0) and end (t1) of the rehabilitation program, as well as 3 months (t2) after rehabilitation, patients completed questionnaires about health-related quality of life (SF-36), sociodemographic and clinical data, attitude towards TCM (including acupuncture), pain (quality, intensity, duration), and adverse events.	Yes, a three month follow up was performed and included in the data in the paper

Was the Acupuncture used in addition to other type of therapy?	All patients participated in a standardized 21-day inpatient rehabilitation program according to current German guidelines. Tui na massage and a magnet lamp were additionally used at the discretion of the TCM physicians.	Yes, all patients receive the normal rehabilitative treatment, and the intervention group received tui na and heat lamp therapy at the discrection of the TCM doctors
Do I agree with the study outcomes?	One hundred and twenty-seven patients (88.8%) wanted TCM to be integrated as standard in inpatient rehabilitation programs, only 1 patient (0.7%) explicitly did not, and 15 patients (10.5%) were undecided. One hundred and nineteen patients (83.2%) said they would be willing to pay for TCM if necessary, 23 (16.1%) would not, and 1 (0.7%) was undecided. At the beginning of the rehabilitation program (t0), groups A (intervention) and B (control) did not differ significantly on the SF-36. On the scale of physical functioning, both groups improved from t0 to t1, with no significant difference between groups. However, with regard to the interval t0 to t2, groups A and B differed significantly, with superior results in group A. Physical role scores favored group A, with no significant difference between groups; for bodily pain, both groups showed a non-significant improvement from t0 to t1. With respect to vitality, the two groups differed significantly from t0 to t2, favoring group A. General health also differed significantly in favor of group A from t0 to t1 (improvement) and from t0 to t2 (deterioration). Finally, emotional role showed a non-significant improvement in both groups from t0 to t1 and a significant deterioration from t0 to t2; deterioration was worse in group B. Social functioning and mental health did not significantly differ between groups The development of pain upon sitting or standing (t0 to t2) showed significantly more favorable results in group A (improvement in 64.1% versus 36.9% of patients; p = 0.009). For pain upon carrying loads of 5 kg or less, no significant difference was noted between groups (p = 0.098), but group A showed better results. With regard to	Yes, outcomes were either more favorable for the intervention group or the same as the control group

	loads of 10 kg or greater, there was a significant difference between groups for t0 to t2 (p = 0.02), with more favorable outcomes in group A. No significant difference was seen concerning pain when walking, but with regard to paresthesias, group A showed more favorable results (t0 to t1, p = 0.01; t0 to t2, p = 0.04).	

Checklist of STRICTA items for the above (Study Article #5).

Intervention	**Description of Item**	**Answer**
1) Acupuncture rationale	1a) Style of acupuncture 1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) 1c) Literature sources to justify rationale	Yes Yes No
2) Needling details	2a) Points used (uni/bilateral) 2b) Numbers of needles inserted 2c) Depths of insertion (e.g. *cun* or tissue level) 2d) Responses elicited (e.g. *de qi* or twitch response) 2e) Needle stimulation (e.g. manual or electrical) 2f) Needle retention time 2g) Needle type (gauge, length, and manufacturer)	No No No No No No Yes
3) Treatment regimen	3a) Number of treatment sessions 3b) Frequency of treatment	Yes Yes
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	Yes
5) Practitioner background	5a) Duration of relevant training 5b) Length of clinical experience 5c) Expertise in specific condition	Yes Yes No
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) 6b) Explanations given to patients of treatment and control interventions 6c) Details of control intervention (precise description, as for Item 2 above, and other items if different) 6d) Sources that justify choice of control	Yes No Yes No

Study #5 showed an significant improvement in SF-36 scores after the three month post treatment follow up for chronic low back pain. In addition, 88.8% of the 160 patient population stated that they

wanted TCM to be integrated as standard in inpatient rehabilitative programs, with 83.2% of the total population saying they would be willing to pay for it if necessary. Lastly it was shown that there was a significant improvement in the reduction of pain upon sitting or standing and pain associated when carrying loads of 10 kg or greater.

FINDINGS

All of the clinical trials were conducted in Europe, particularly Germany [2, 3, 4, 5] most likely because their healthcare system adequately covers alternative care well. The remaining study was conducted in Spain [1]. Three of the studies [1, 2, 3] included the points they used, while the remaining [3, 4, 5] relied upon the experience of the practitioner on a case by case basis. In only two of the studies [1, 2] were the assessors of treatment results blinded, while one study [4] did not report whether or not the assessors were blinded. Only one of the clinical trials [3] specifically asked the patient to guess whether or not they had received a control or experimental intervention. All of the studies included therapies other than manually manipulated acupuncture needles. In three of the five studies [2, 4, 5] this additional therapy included medical intervention that would normally be done for patients suffering from chronic pain due to orthopedic issues. In the other two studies [1, 3] the additional therapy included optional western medications and in the case of the first study [1], electrostimulation of the needles.

All studies reported findings which stated that acupuncture when combined with other synergistic modalities had a more positive and lasting effect than receiving the usual western modalities alone. Specifically:

- Study # 1 showed a significantly greater improvement in pain in the intervention group than in the sham acupuncture group as measured by VAS (visual analogue scale), Lattinen Index, and SPADI (shoulder pain and disability index) scale. In addition to this, the intervention group also showed a greater improvement in range of motion and a lowered use of diclofenac (NSAID). All of these metrics were maintained when measured again after the treatments stopped at a six month follow up.
- Study #2 showed a significant decrease in VAS, a similar decrease pain of 50% or more, and a similar improvement on a 4-PBS (four point box scale) in the acupuncture and

sham groups when combined with standard orthopedic treatment immediately following the end of treatment. However, none of these were maintained in the sham group when measured again 3 months post treatment.

- Study #3 showed that there was no significant difference when treating chronic low back pain whether using individualized care using traditional Chinese medicine metrics or by using a selection of commonly used points for back pain from a previous study by the same group
- Study #4 showed the people receiving acupuncture along with standard western medical care had a more pronounced improvement (as measured by a validated neck pain and disability scale developed by Wheeler et al., 1999) in neck pain and disability three months post treatment. Quality of life scores (physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, mental health) as measured by the SF-36 (short form 36) subscale also showed a significantly pronounced improvement in the intervention versus the control group at the end of the three month follow up.
- Study #5 showed an significant improvement in SF-36 scores after the three month post treatment follow up for chronic low back pain. In addition, 88.8% of the 160 patient population stated that they wanted TCM to be integrated as standard in inpatient rehabilitative programs, with 83.2% of the total population saying they would be willing to pay for it if necessary. Lastly it was shown that there was a significant improvement in the reduction of pain upon sitting or standing and pain associated when carrying loads of 10 kg or greater.

CONCLUSION

In conclusion, from a handful of studies this review has shown the effectiveness of acupuncture when combined with standard non-invasive western modalities. All studies showed significant ($p < 0.005$) improvements of the intervention, usually acupuncture and standard western modalities, over the control groups, standard modalities on their own. This is especially apparent during the follow up measurements taken after the respective treatments had ended. In some cases immediate relief of a non-significant difference ($p >= 0.005$) was felt by both intervention and control groups, but in no study did the relief provided by the control groups last up to the follow up collection of metrics. Therefore it is

the opinion of this study that orthopedic pain management and rehabilitative centers should begin to include licensed and experienced acupuncture practitioners in their practices.

In addition to reduction in pain, one study [3] also showed that there was no significant difference between an individualized treatment based on traditional Chinese medicine metrics and standardized treatment consisting of the same group of points for each person. While some practitioners may lament this, this may be good for patients as it may result in a subspecialty of acupuncture which would theoretically allow for quicker training of practitioners and thus a wider availability of the treatment. However, this was only one study with 150 patients and a single acupuncture practitioner, albeit the study claimed that this person specialized in chronic low back pain. Therefore, more studies with a wider array of practitioners should be done before any conclusions about what this means for the future of orthopedic acupuncture are drawn.

REFERENCE LIST

Guerra de Hoyos JA, Andrés Martín Mdel C, Bassas y Baena de Leon E, Vigára Lopez M, Molina López T, Verdugo Morilla FA, González Moreno MJ. (2004). Randomised trial of long term effect of acupuncture for shoulder pain. Pain. 2004 Dec;112(3):289-98.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15561384

Molsberger AF, Mau J, Pawelec DB, Winkler J. (2002). Does acupuncture improve the orthopedic management of chronic low back pain--a randomized, blinded, controlled trial with 3 months follow up. Pain. 2002 Oct;99(3):579-87.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12406534

Pach D, Yang-Strobel X, Lüdtke R, Roll S, Icke K, Brinkhaus B, Witt CM. (2013). Standardized versus Individualized Acupuncture for Chronic Low Back Pain: A Randomized Controlled Trial. Evid Based Complement Alternat Med. 2013;2013:125937.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24288556

Witt CM, Jena S, Brinkhaus B, Liecker B, Wegscheider K, Willich SN. (2006). Acupuncture for patients with chronic neck pain. Pain. 2006 Nov;125(1-2):98-106.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/16781068

Weiss J, Quante S, Xue F, Muche R, Reuss-Borst M. (2013). Effectiveness and acceptance of acupuncture in patients with chronic low back pain: results of a prospective, randomized, controlled trial. J Altern Complement Med. 2013 Dec;19(12):935-41.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23738680