Acupuncture in Patients With Chronic Low Back Pain

A Randomized Controlled Trial

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Background: Acupuncture is widely used by patients with low back pain, although its effectiveness is unclear. We investigated the efficacy of acupuncture compared with minimal acupuncture and with no acupuncture in patients with chronic low back pain.

Methods: Patients were randomized to treatment with acupuncture, minimal acupuncture (superficial needling at nonacupuncture points), or a waiting list control. Acupuncture and minimal acupuncture were administered by specialized acupuncture physicians in 30 outpatient centers, and consisted of 12 sessions per patient over 8 weeks. Patients completed standardized questionnaires at baseline and at 8, 26, and 52 weeks after randomization. The primary outcome variable was the change in low back pain intensity from baseline to the end of week 8, as determined on a visual analog scale (range, 0-100 mm).

Results: A total of 298 patients (67.8% female; mean ± SD age, 59 ± 9 years) were included. Between baseline and week 8, pain intensity decreased by a mean ± SD of 28.7 ± 30.3 mm in the acupuncture group, 23.6 ± 31.0 mm in the minimal acupuncture group, and 6.9 ± 22.0 mm in the waiting list group. The difference for the acupuncture vs minimal acupuncture group was 5.1 mm (95% confidence interval, −3.7 to 13.9 mm; $P = .26$), and the difference for the acupuncture vs waiting list group was 21.7 mm (95% confidence interval, 13.9-30.0 mm; $P < .001$). Also, at 26 ($P = .96$) and 52 ($P = .61$) weeks, pain did not differ significantly between the acupuncture and the minimal acupuncture groups.

Conclusion: Acupuncture was more effective in improving pain than no acupuncture treatment in patients with chronic low back pain, whereas there were no significant differences between acupuncture and minimal acupuncture.

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CHRONIC LOW BACK PAIN IS a major health problem in Western countries, and is associated with high medical expenses, lost productivity, and disability.[1,2] Although a wide range of standard treatments are available, their effectiveness is still unclear.[3] In 1997, one third of adults with low back pain in the United States were treated by a complementary and alternative medicine provider.[4] Among the more commonly used complementary and alternative medicine treatment strategies, acupuncture is used frequently in patients with low back pain.[5,6] However, previous systematic reviews[7-9] of acupuncture for the treatment of low back pain yielded inconclusive results.

In the Acupuncture Randomized Trial in Low Back Pain, we investigated whether acupuncture was more efficacious in reducing pain than minimal acupuncture or no acupuncture in patients with chronic low back pain.

METHODS

PROTOCOL, DESIGN, AND RANDOMIZATION

The Acupuncture Randomized Trial in Low Back Pain was a randomized, controlled, multicenter trial comparing acupuncture with minimal acupuncture and with a no acupuncture waiting list control. Minimal acupuncture served as a sham intervention; the additional no acupuncture waiting list control was included because minimal acupuncture may not be a physiologically inert placebo. In the acupuncture and minimal acupuncture groups, patients were blinded with regard to treatment. The Acupuncture Randomized Trial in Low Back Pain was part of a larger acupuncture project initiated by the German Federal Committee of Physicians and Health Insurers. The committee recommended that studies be conducted on the efficacy of acupuncture in the treatment of pain for 3 diseases, including chronic low back pain. The methods used in this trial and the results of the other 3 trials have been described in detail elsewhere.[10-13]

Patients were randomized in a 2:1:1 (acupuncture–minimal acupuncture–waiting list) ratio using a centralized telephone randomization procedure (a randomized list was generated using computer software [SAMPSIZE V2.0]).

The study was performed according to common guidelines for clinical trials (Declaration of Helsinki, version Edinburgh 2000, International Conference on Harmonisation Good Clinical Practice, including certification by external audit). The protocol was approved by the local ethics review boards in all regions where the study was conducted. All study participants provided written informed consent.

PARTICIPANTS

Most participants were recruited through articles in local newspapers; a few patients spontaneously contacted trial centers. The inclusion criteria were as follows: clinical diagnosis of chronic low back pain with a disease duration of more than 6 months (further diagnostic results were not required), aged 40 to 75 years, average pain intensity of 40 or more on a 100-mm visual analog scale on the previous 7 days, only use of oral nonsteroidal anti-inflammatory drugs for pain treatment in the 4 weeks before treatment, and written consent.

The main exclusion criteria were as follows: protrusion or prolapse of 1 or more intervertebral discs with concurrent neurological symptoms; radicular pain; prior vertebral column surgery; infectious spondylopathy; low back pain caused by inflammatory, malignant, or autoimmune disease; congenital deformation of the spine (except for slight lordosis or scoliosis); compression fracture caused by osteoporosis; spinal stenosis; spondylolysis or spondylolisthesis; patients with Chinese medicine diagnoses warranting treatment with moxibustion (determined by trial physicians); and any acupuncture treatment during the past 12 months.

INTERVENTIONS

The selection criteria of acupuncture physicians were as follows: at least 140 hours of acupuncture training (median, 350 hours), at least 3 years of experience (median, 10 years) in acupuncture treatment, and participation in the investigators' meetings. The treatment strategies for acupuncture and minimal acupuncture were developed in a consensus process with acupuncture experts from 2 major German societies for medical acupuncture.

The acupuncture and minimal acupuncture treatments consisted of 12 sessions of 30 minutes' duration, each administered over 8 weeks (usually 2 sessions in each of the first 4 weeks, followed by 1 session per week in the remaining 4 weeks).

Acupuncture treatment was semistandardized. All patients were treated with a selection of local and distant points, including (bilaterally) at least 4 local points from the following selection: bladder 20 to 34; bladder 50 to 54; gallbladder 30; governing vessel 3, 4, 5, and 6; and extraordinary points Huatojiaji and Shiqizhuixia. Also, physicians selected and needled bilaterally at least 2 distant points from the following sample: small intestine 3; bladder 40, 60, and 62; kidney 3 and 7; gallbladder 31, 34, and 41; liver 3; and governing vessel 14 and 20. In the event that patients were experiencing local or pseudoradicular sensation, at least 2 local points were acupunctured. In addition, other acupuncture points, including ear and trigger points, could be chosen individually. Sterile, disposable, 1-time needles had to be used; needle length and diameter were not predefined. Physicians were instructed to achieve *de qi* (an irradiating feeling), if possible. Needles were to be stimulated manually at least once during each session.

The number, duration, and frequency of the sessions in the minimal acupuncture group were the same as for the acupuncture group.[10] In each session, at least 6 of 10 predefined nonacupuncture points were needled bilaterally using a superficial insertion with fine needles (length, 20-40 mm). These points were not in the area of the lower back where the patients were experiencing pain. *De qi* and manual stimulation of the needles were avoided. All acupuncturists received a videotape, oral instruction, and a brochure showing detailed information on minimal acupuncture.

Patients in the waiting list group did not receive acupuncture treatment for 8 weeks after randomization. After that period, they received 12 sessions of the acupuncture treatment previously described.

Patients were allowed to treat chronic low back pain with oral nonsteroidal anti-inflammatory drugs, if required. The use of corticosteroids or pain-relieving drugs that act through the central nervous system was prohibited.

Patients were informed about acupuncture and minimal acupuncture in the study as follows: "In this study, different types of acupuncture will be compared. One type is similar to the acupuncture treatment used in China. The other type does not follow these principles, but has also been associated with positive outcomes in clinical studies."

OUTCOME MEASUREMENT

All patients completed a modified version of the pain questionnaire published by the German Society for the Study of Pain at baseline and after 8, 26, and 52 weeks (**Figure 1**).

The pain questionnaire includes questions on sociodemographic characteristics, pain intensity (visual analog scale), back function (validated German questionnaire Funktionsfragebogen Hannover-Rücken),[14] global assessment of treatment effects, and the following validated scales: (1) the German version of the Pain Disability Index,[15] (2) a scale for assessing the emotional aspects of pain (Schmerzempfindungsskala),[16] (3) a depression scale (Allgemeine Depressionsskala),[17] and (4) the German version of the 36-Item Short-Form Quality of Life Questionnaire to assess health-related quality of life.[18] The number of days with pain and taking pain medication was documented in a diary by the patients between baseline and week 8. The primary outcome variable was the change in low back pain intensity from baseline to the end of week 8 after randomization, as measured by a visual analog scale (range, 0-100 mm).

The trial physicians documented medical history and examination results at baseline, study intervention in detail, and any serious adverse events. In addition, adverse effects were documented by patients at the end of week 8. To test blinding to treatment and assess the credibility of the respective treatment methods, patients complete a credibility questionnaire after the third acupuncture session.[19] At the end of the study, patients were asked whether they thought they had received acupuncture following the principles of Chinese medicine or the other type of acupuncture.

STATISTICAL ANALYSIS

Confirmatory testing of the primary outcome variable (change of low back pain intensity measured by a visual analog scale at the end of week 8) and all main analyses (using a commercially available software program [SPSS 11.5; SPSS Inc, Chicago, Ill]) were based on the intention-to-treat population using all available data (complete cases) at week 8. Sensitivity analyses were performed for the primary outcome measure by replacing missing data with multiple imputations and last value carried forward using computer software (SOLAS 3.0; Statistical Solutions, Cork, Ireland).

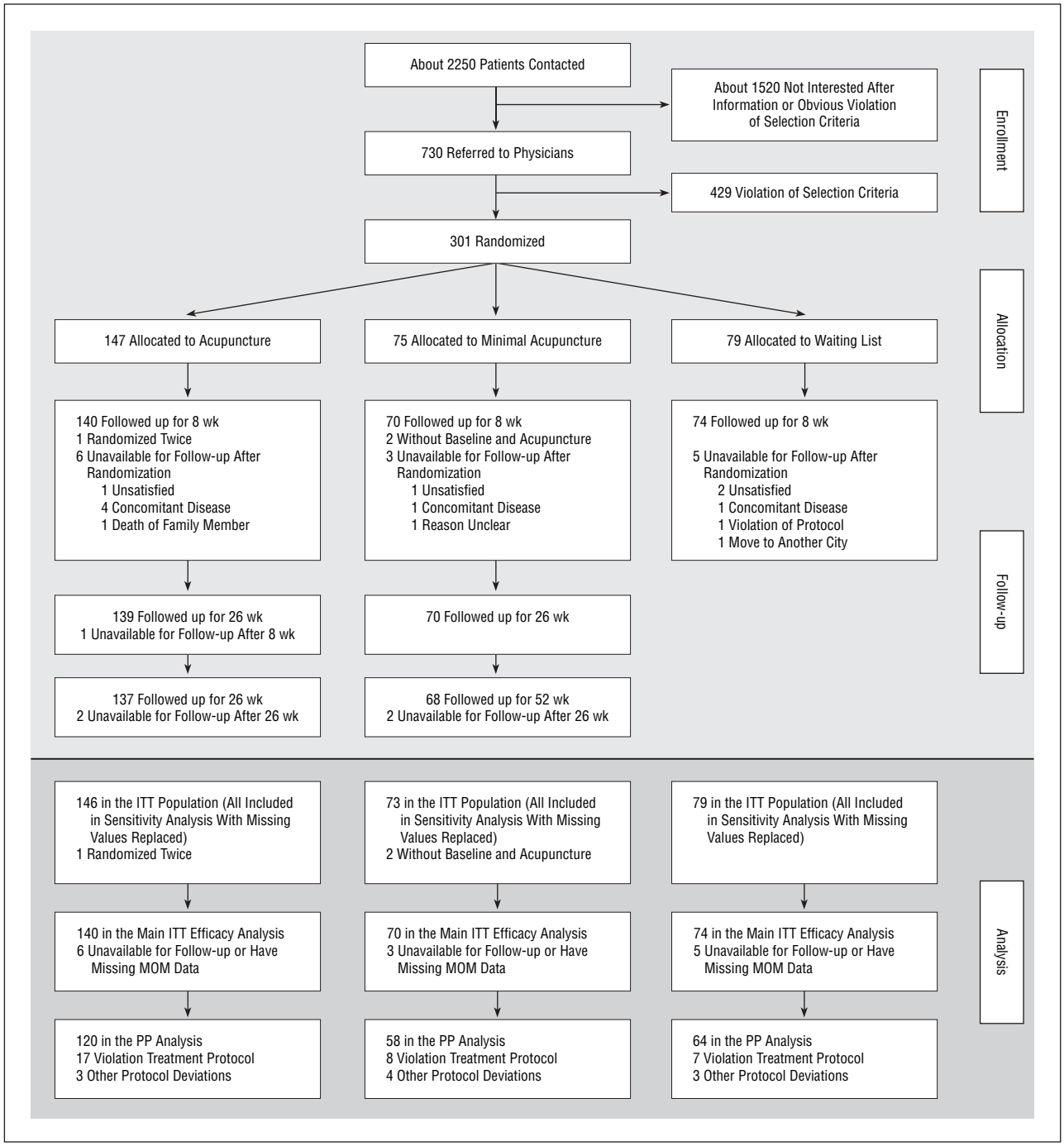

Figure 1. Trial flowchart of the acupuncture randomized trial low back pain. ITT indicates intention to treat; MOM, main outcome measure; and PP, per protocol.

A priori–ordered 2-sided null hypothesis was tested using the *t* test (significance level, .05). In a first step, it was investigated whether acupuncture was more efficacious than no treatment; and in a second step (only if the first null hypothesis was rejected), whether acupuncture was more efficacious than minimal acupuncture. Moreover, an analysis of covariance was performed to account for potential baseline differences. We performed exploratory analyses for the secondary outcome measures using 2-sided *t* tests and χ^2 tests for pairwise comparisons of groups without adjusting for multiple testing. A per-protocol analysis was performed, which included only patients with no major protocol violations by the end of week 8. The waiting list group was included in the main analysis only until the end of week 8 after randomization.

The study was powered to detect a group difference of 10 mm in the main outcome measure with 80% power, assuming an SD of 22.5 mm in the primary outcome in both groups and a 2-sided significance level of 5%.

RESULTS

PARTICIPANTS, TREATMENT, AND BLINDING

Between March 12 and September 20, 2002, about 2250 patients with chronic low back pain expressed interest

Table 1. Baseline Characteristics*

Characteristic	All Patients (N = 298)	Acupuncture Group (n = 146)	Minimal Acupuncture Group (n = 73)	Waiting List Group (n = 79)
Sex†				
Female	202 (67.8)	93 (63.7)	55 (75.3)	54 (68.4)
Male	96 (32.2)	53 (36.3)	18 (24.7)	25 (31.6)
Age, y	58.8 ± 9.1	59.1 ± 8.8	58.2 ± 9.4	58.9 ± 9.5
Body mass index‡	26.6 ± 4.3	26.7 ± 4.2	26.2 ± 4.6	26.9 ± 4.3
Duration of low back pain, y	14.7 ± 11.1	14.7 ± 11.0	13.6 ± 10.5	15.8 ± 11.8
Time with pain (within 1 mo), d	25.2 ± 7.7	24.6 ± 8.1	26.2 ± 7.6	25.4 ± 7.0
Time with limited function (past 6 mo), d	96.3 ± 61.4	88.0 ± 58.0	103.3 ± 64.4	105.4 ± 63.2
Prior acupuncture treatment†	98 (32.9)	47 (32.2)	26 (35.6)	25 (31.6)
Physiotherapy in the past 6 mo†	86 (28.9)	38 (26.0)	21 (28.8)	27 (34.2)
Use of analgesics in the past 6 mo†	112 (37.6)	59 (40.4)	27 (37.0)	26 (32.9)
Low back pain intensity, VAS score	64.8 ± 14.0	63.2 ± 13.2	66.6 ± 15.7	66.1 ± 13.6
Back function, FFbH-R score§	57.0 ± 8.6	57.1 ± 18.6	57.2 ± 17.3	56.7 ± 20.0
Disability, PDI score	30.1 ± 11.8	28.9 ± 11.1	31.5 ± 11.1	31.0 ± 13.3
SF-36 score§				
Physical health	32.3 ± 8.2	32.8 ± 8.2	31.8 ± 8.3	31.6 ± 8.2
Mental health	48.9 ± 11.0	48.5 ± 10.7	48.0 ± 11.1	50.7 ± 11.3
Subscale pain	34.1 ± 14.2	35.2 ± 14.8	32.5 ± 13.1	33.5 ± 14.0
SES, *t* standard scores				
Affective pain	50.3 ± 8.6	50.2 ± 8.4	50.9 ± 8.2	50.0 ± 9.3
Sensory pain	49.6 ± 9.4	49.7 ± 9.1	49.1 ± 8.4	49.8 ± 11.1
Depression, ADS, *t* standard scores	52.4 ± 8.0	53.0 ± 7.7	53.0 ± 7.3	51.0 ± 9.0

Abbreviations: ADS, Allgemeine Depressionsskala (depression scale); FFbH-R, Funktionsfragebogen Hannover-Rücken (back function questionnaire); PDI, Pain Disability Index; SES, Schmerzempfindungsskala (questionnaire for assessing the emotional aspects of pain); SF-36, 36-Item Short-Form Quality of Life Questionnaire; VAS, visual analog scale.

*Data are given as mean ± SD unless otherwise indicated.

†Data are given as number (percentage) of each group.

‡Calculated as weight in kilograms divided by the square of height in meters.

§Higher values indicate better status.

in participating in the study, and a total of 301 patients were randomized (Figure 1). Three patients were excluded from the intention-to-treat analysis (1 was randomized twice and 2 without baseline data did not receive the study intervention). All of the remaining 298 patients (146 in the acupuncture group, 73 in the minimal acupuncture group, and 79 in the waiting list group) treated in a total of 30 outpatient centers were included in the intention-to-treat population.

Complete data were available for 284 (95.3%) of the patients at the end of week 8. At weeks 26 and 52, follow-up data were available for 95.4% and 93.6% of the 219 intention-to-treat patients allocated to the acupuncture and minimal acupuncture groups, respectively. The per-protocol analysis included 242 patients (120 in the acupuncture group, 58 in the minimal acupuncture group, and 64 in the waiting list group), 81.2% of the 298 patients.

The baseline characteristics of the 3 treatment groups were similar (**Table 1**). About one third of the participants had had previous experience with acupuncture. The mean ± SD number of needles per session was 17 ± 4 (acupuncture group) and 12 ± 1 (minimal acupuncture group). After 3 treatment sessions, patients rated the credibility of acupuncture and minimal acupuncture almost identically (**Table 2**). At the end of the study, their guesses as to which group they had been allocated to differed significantly ($P = .04$) between groups. Of the 137 participants in the acupuncture group with available data, 86 (62.8%) believed they received Chinese acupuncture, 26 (19.0%) believed they received the other type of acupuncture, and 25 (18.2%) said they did not know which type of acupuncture they received. Of the 68 participants in the minimal acupuncture group with available data, 31 (45.6%) believed they received Chinese acupuncture, 15 (22.1%) believed they received the other type of acupuncture, and 22 (32.4%) did not know which type of acupuncture they received. (Percentages may not total 100 because of rounding.)

Table 2. Data on th e Credibility of the Treatment After the Third Treatment Session*

Credibility After the Third Session	Acupuncture Group (n = 145)*	Minimal Acupuncture Group (n = 71)*	*P* Value (2-Sided)
Improvement expected	5.0 ± 1.1	5.0 ± 1.0	.93
Recommendation to others	5.5 ± 1.0	5.3 ± 1.2	.12
Treatment logical	4.9 ± 1.1	4.7 ± 1.4	.20
Effective also for other diseases	5.5 ± 1.0	5.4 ± 1.1	.49

*Data are given as mean ± SD scores (0 indicates minimal agreement; and 6, maximal agreement).

EFFICACY

According to the intention-to-treat analyses including complete cases, the pain intensity decreased from baseline to week 8 by a mean ± SD of 28.7 ± 30.3 mm in the acupunc-

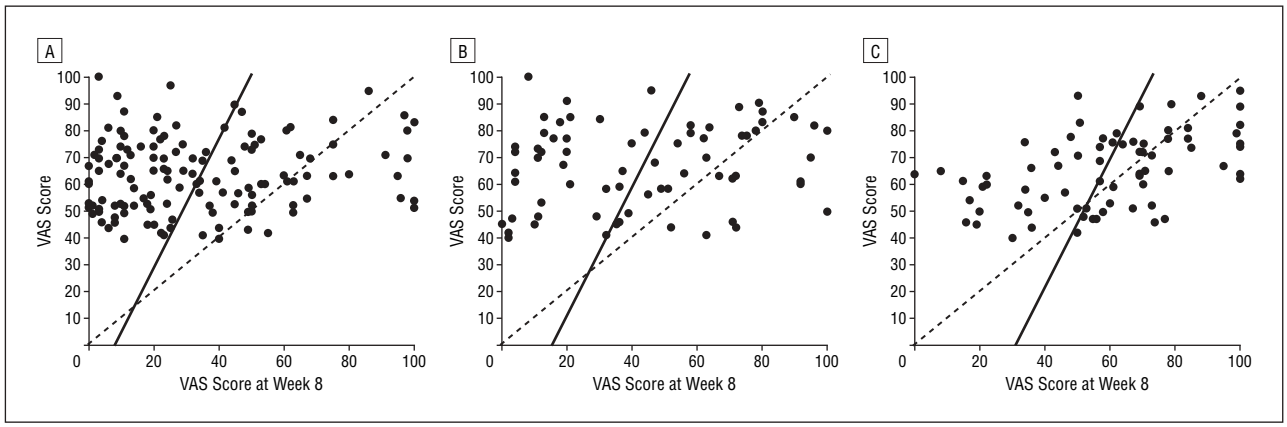

Figure 2. Scatterplots of the acupuncture group (A), the minimal acupuncture group (B), and the waiting list group (C). VAS indicates visual analog scale.

ture group, 23.6±31.0 mm in the minimal acupuncture group, and 6.9±22.0 mm in the waiting list group. The difference for the acupuncture vs minimal acupuncture group was 5.1 mm (95% confidence interval, –3.7 to 13.9 mm; $P=.26$); and for the acupuncture vs waiting list group, 21.7 mm (95% confidence interval, 13.9-30.0 mm; $P<.001$). The treatment effect for individual patients categorized with respect to treatment group is displayed in **Figure 2**.

The results were similar if missing values were replaced, and if baseline values were entered in the analysis of covariance as covariates. In addition, the per-protocol analysis showed similar results. The proportion of responders (at least 50% reduction of pain intensity) was 54.0% in the acupuncture group compared with 38.6% in the minimal acupuncture group and 14.9% in the waiting list group.

After 8 weeks, there were significant differences in 10 of 12 predefined secondary outcome measures between the acupuncture and waiting list groups, and in 6 of 12 outcomes between the acupuncture and minimal acupuncture groups (**Table 3**).

After 26 and 52 weeks, results in the acupuncture group tended to be better than in the minimal acupuncture group for all outcome measures (**Table 4**). However, except for days with limited function at 26 weeks and the mental health and the subscale pain of the 36-Item Short-Form Quality of Life Questionnaire at 52 weeks, there were no significant differences between the groups. The development of low back pain intensity is presented in **Figure 3**. The patients in the waiting list group showed improvements after receiving acupuncture between weeks 9 and 16; these improvements were similar to those seen in patients in the acupuncture group.

SAFETY

A total of 22 serious adverse events (13 in the acupuncture group, 4 in the minimal acupuncture group, and 5 in the waiting list group) were documented. Nineteen patients received inpatient treatment. Furthermore, 2 patients reported serious adverse events, but treatment in the hospital was not necessary. One patient (in the minimal acupuncture group) committed suicide after the end of treatment because of personal problems. However, all these cases were considered unrelated to study treatment. Fifteen patients (10.7%) receiving acupuncture and 12 patients (17.1%) receiving minimal acupuncture ($P=.20$) reported adverse effects. The most commonly reported adverse effects were hematoma and bleeding.

COMMENT

In the present study, acupuncture was more effective than no acupuncture in patients with chronic low back pain. Most outcome variables tended to be slightly better in the acupuncture group compared with the minimal acupuncture group. However, there were no significant differences with regard to the main outcome measure after 8, 26, or 52 weeks.

To our knowledge, this is one of the largest and most rigorous trials to investigate the efficacy of acupuncture for low back pain. Its strengths include central randomization, assessment of the credibility of interventions, interventions based on expert consensus provided by qualified and experienced medical acupuncturists, and high follow-up rates. Because most study participants expressed high expectations of acupuncture treatment, the study population may not be entirely representative of all patients with chronic low back pain in clinical practice.

It was not possible to blind participating physicians to the treatment used, but all important outcome measures were assessed independently by patients using questionnaires and diaries, which were sent directly to them by the study coordination center. Although patients receiving acupuncture and minimal acupuncture rated the credibility of the interventions almost identically after 3 sessions, the question on allocation posed at the end of the trial reveals some degree of unblinding.

The consensus-based semistandardized study intervention in our trial represents a compromise between flexibility (as desired by acupuncturists) and reproducibility (as desired by researchers). We consider the intervention to have been suitable. Nevertheless, it is impossible to predict whether our findings would have been different if another acupuncture strategy had been used. In addition, it is possible that the selection of the participating trial acupuncturist had an effect on the study results. Thus, it is important to emphasize that this study, like all other acupuncture studies, does not investigate

Table 3. Primary and Secondary Outcomes at Week 8 After Randomization (Questionnaire) and at Weeks 5 to 8 (Diary) (ITT Analyses)

Variable	Acupuncture Group (n = 140)*	Minimal Acupuncture Group (n = 70)*	Waiting List Group (n = 74)*	Acupuncture vs Minimal Acupuncture Group		Acupuncture vs Waiting List Group	
				Change, Mean (95% CI)†	*P* Value‡	Change, Mean (95% CI)†	*P* Value‡
Primary outcome							
Difference in LBP intensity between baseline and week 8, VAS score§	28.7 ± 30.3	23.6 ± 31.0	6.9 ± 22.0	5.1 (–3.7 to 13.9)	.26	21.7 (13.9 to 30.0)	<.001
Secondary outcomes							
LBP intensity, VAS score§	34.5 ± 28.5	43.7 ± 29.8	58.6 ± 25.1	–9.1 (–17.5 to –0.8)	.03	–24.1 (–31.9 to –16.3)	<.001
Back function, FFbH-R score‖	66.8 ± 18.3	62.9 ± 20.3	57.7 ± 19.9	3.9 (–1.8 to 9.6)	.17	9.1 (3.7 to 14.4)	.001
Disability, PDI score	18.8 ± 13.1	21.5 ± 13.2	27.1 ± 14.1	–2.7 (–6.5 to 1.1)	.16	–8.2 (–12.0 to –4.4)	<.001
SF-36 score‖							
Physical health	40.5 ± 9.7	36.2 ± 10.3	33.9 ± 9.5	4.3 (1.4 to 7.2)	.004	6.6 (3.8 to 9.3)	<.001
Mental health	50.6 ± 9.5	51.0 ± 9.8	49.4 ± 11.5	–0.4 (–3.2 to 2.4)	.79	1.2 (–1.9 to 4.3)	.46
Subscale pain	58.8 ± 22.7	50.7 ± 20.1	39.9 ± 17.8	8.0 (1.7 to 14.3)	.01	18.8 (13.3 to 24.4)	<.001
SES, *t* standard score							
Affective pain	41.2 ± 7.9	43.6 ± 8.0	47.5 ± 10.0	–2.4 (–4.7 to –0.1)	.04	–6.3 (–8.7 to –3.8)	<.001
Sensory pain	44.5 ± 8.1	45.7 ± 8.3	50.0 ± 11.4	–1.3 (–3.7 to 1.1)	.29	–5.6 (–8.6 to –2.6)	<.001
Depression, ADS, *t* standard scores	48.9 ± 9.0	49.4 ± 9.3	49.7 ± 10.4	–0.5 (–3.3 to 2.3)	.73	–0.8 (–3.7 to 2.1)	.58
Time with limited function (past 2 mo), d	17.0 ± 16.5	24.0 ± 19.7	26.5 ± 19.1	–7.0 (–12.4 to –1.6)	.01	–9.5 (–14.4 to –4.5)	<.001
Time with pain in week 8 (diary), d	3.8 ± 2.8	4.4 ± 2.8	6.2 ± 1.6	–0.6 (–1.5 to 0.2)	.13	–2.4 (–3.0 to –1.8)	<.001
Time with analgesics in weeks 5-8 (diary), d	2.0 ± 4.8	4.9 ± 8.3	6.3 ± 8.7	–2.9 (–5.0 to –0.8)	.009	–4.3 (–6.5 to –2.0)	<.001

Abbreviations: ADS, Allgemeine Depressionsskala (depression scale); CI, confidence interval; FFbH-R, Funktionsfragebogen Hannover-Rücken (back function questionnaire); ITT, intention to treat; LBP, low back pain; PDI, Pain Disability Index; SES, Schmerzempfindungsskala (questionnaire for assessing the emotional aspects of pain); SF-36, 36-Item Short-Form Quality of Life Questionnaire; VAS, visual analog scale.
*Data are given as mean ± SD.
†Minor discrepancies between differences calculated from group means presented in the table and change are because of rounding.
‡From 2-sided *t* tests.
§The VAS range is from 0 to 100 mm.
‖Higher values indicate better results.

Table 4. Secondary Outcome Variables After 26 and 52 Weeks (ITT Analyses)

Questionnaire	26 Weeks				52 Weeks			
	Acupuncture Group*	Minimal Acupuncture Group*	Acupuncture vs Minimal Acupuncture Group		Acupuncture Group*	Minimal Acupuncture Group*	Acupuncture vs Minimal Acupuncture Group	
			Change, Mean (95% CI)†	*P* Value‡			Change, Mean (95% CI)†	*P* Value‡
Low back pain intensity, VAS score§	38.4 ± 29.8	42.1 ± 30.3	–3.8 (–12.4 to 4.9)	.39	39.2 ± 29.2	44.9 ± 30.4	–5.7 (–14.4 to 3.0)	.20
Back function, FFbH-R score‖	66.0 ± 20.1	64.1 ± 22.9	1.9 (–4.2 to 8.0)	.53	66.0 ± 20.4	63.1 ± 21.6	2.9 (–3.2 to 9.0)	.35
Disability, PDI score	19.3 ± 13.9	21.4 ± 15.6	–2.1 (–6.3 to 2.1)	.33	19.0 ± 13.4	23.0 ± 15.0	–4.0 (–8.1 to 0.1)	.06
SF-36 score‖								
Physical health	39.3 ± 9.9	37.6 ± 11.3	1.7 (–1.3 to 4.7)	.27	38.9 ± 10.0	36.1 ± 10.3	2.8 (–0.2 to 5.7)	.07
Mental health	49.9 ± 10.0	46.8 ± 12.9	3.1 (–0.5 to 6.6)	.09	50.5 ± 10.4	47.2 ± 11.9	3.3 (0.1 to 6.5)	.04
Subscale pain	53.6 ± 22.9	49.6 ± 23.6	3.9 (–2.7 to 10.7)	.24	52.4 ± 23.2	44.0 ± 22.9	8.5 (1.7 to 15.2)	.01
SES, *t* standard score								
Affective pain	42.1 ± 9.2	43.0 ± 8.9	–0.9 (–3.5 to 1.7)	.50	41.8 ± 9.2	43.8 ± 8.8	–2.0 (–4.7 to 0.7)	.14
Sensory pain	45.1 ± 9.5	45.3 ± 8.6	–0.2 (–2.9 to 2.5)	.88	45.4 ± 10.3	46.3 ± 9.4	–0.9 (–3.8 to 2.1)	.56
Depression, ADS, *t* standard scores	49.7 ± 8.6	50.3 ± 10.7	–0.6 (–2.5 to 3.7)	.69	48.2 ± 9.1	50.7 ± 9.7	–2.5 (–5.3 to 0.4)	.09
Time with limited function (past 6 mo), d	40.9 ± 42.3	59.5 ± 53.7	–18.6 (–33.3 to –3.9)	.01	42.4 ± 56.3	52.9 ± 57.1	–10.5 (–27.0 to 6.1)	.21

Abbreviations: See Table 3.
*Data are given as mean ± SD.
†Minor discrepancies between differences calculated from group means presented in the table and change are because of rounding.
‡From 2-sided *t* tests.
§The VAS range is from 0 to 100 mm.
‖Higher values indicate better results.

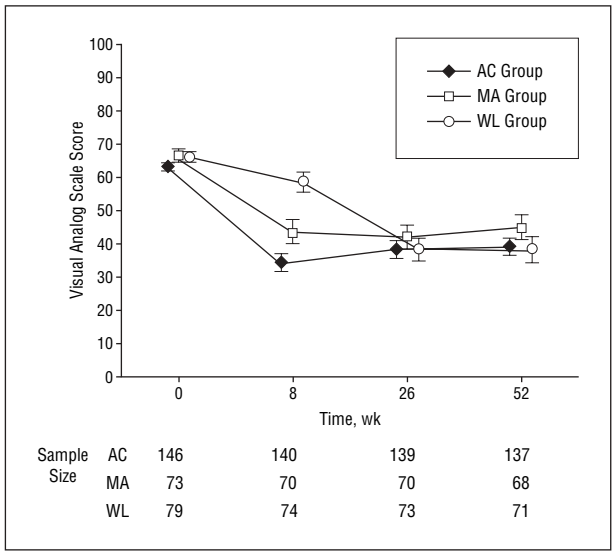

Figure 3. Mean±SE development of low back pain intensity in the 3 treatment groups. AC indicates acupuncture; MA, minimal acupuncture; and WL, waiting list.

the effectiveness of acupuncture in general, but rather the effectiveness of a specific acupuncture intervention.

In agreement with our findings, 2 recently published meta-analyses[20,21] have demonstrated that acupuncture is more effective for pain relief and functional improvement than no treatment in patients with chronic low back pain. However, in contrast to earlier systematic reviews,[8,9] these meta-analyses show that acupuncture is also more effective than sham treatment for short-term pain relief. With regard to sham-controlled trials, these meta-analyses report a standardized mean difference (difference between groups divided by the standard deviation) of 0.47[20] and 0.58.[21] The pooled effect size estimates are based on 4 trials. If our main outcome measure were expressed in the same fashion, the effect size would be 0.17 (95% CI, –0.12 to 0.45). This leads to the following question: how can this discrepancy in our study be explained?

First, although our trial is larger than any of the studies included in the 2 previously mentioned meta-analyses, we cannot rule out that a small effect has been missed because of limited power. However, it seems unlikely that the substantially smaller effect size in our trial was due only to random variation. Second, whereas we did not find a significant difference between treatment groups for our main outcome measure (ie, the change in pain intensity from baseline to week 8), the direct comparison of values for pain intensity after 8 weeks did yield a significant difference. This seems to be due to the fact that the baseline values differed slightly between the groups. When we adjusted for baseline values in our covariance analysis, the difference between pain intensity values was just short of statistical significance ($P=.06$). It seems that the authors of both meta-analyses based their calculations on posttreatment pain intensity data and would have, thus, considered our trial to be positive (ie, as having a significant difference). Third, another potential reason for our somewhat contradictory findings could be an overestimation of the effects in the meta-analyses due to publication bias or bias within the published studies.

We assume that one of the main reasons for the nonsignificant result for the primary outcome variable between acupuncture and minimal acupuncture is the particularly strong response to minimal acupuncture in our trial. When comparing patients receiving acupuncture treatment with the no treatment controls, the 2 meta-analyses found standardized mean differences of 0.69 and 0.76. In our trial, the standardized mean differences were 0.78 between acupuncture and waiting list and 0.62 between minimal acupuncture and waiting list for the main outcome measure. This indicates that the absolute effect of acupuncture in our trial was similar to that in the trials included in the meta-analyses. The minimal acupuncture intervention used in our trial probably cannot be considered a physiologically inert placebo. There is evidence that sham acupuncture could also have specific analgesic effects.[22] Indeed, this was 1 of the reasons why we chose to incorporate a no treatment control group in our trial. However, several trials included in the meta-analyses yielded significant results despite the use of similar, or even more invasive, sham interventions.[20,21]

Given the methodological problems associated with sham-controlled trials of acupuncture, there is a strong need for head-to-head comparisons between acupuncture and other interventions used for treating chronic low back pain.[20,21] To our knowledge, only 2 trials[23,24] have been published that compare acupuncture with transcutaneous nerve stimulation (showing a trend in favor of acupuncture) and 1 trial[25] has been published comparing acupuncture with massage (showing a substantially better result for massage on the function outcome, but less benefits in terms of pain).

In conclusion, our findings provide further evidence that patients with chronic low back pain who receive acupuncture experience clinically relevant benefits compared with patients receiving no acupuncture treatment. However, the results also suggest that the correct location of needles plays only a limited role.

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