

Interventions and Physician Characteristics in a Randomized Multicenter Trial of Acupuncture in Patients with Low-Back Pain

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ABSTRACT

Objective: Descriptions of the interventions used in acupuncture studies are often incomplete. The aim of this paper is to describe participating trial physicians and interventions in a randomised trial of acupuncture for low back pain.

Design: Three-armed, randomized, controlled multicenter trial with 1-year follow-up. A total of 301 patients with low-back pain were randomized to 12 sessions of semistandardized acupuncture (at least six local and two distant points needled bilaterally from a selection of predefined points, but individual choice of additional body or ear acupuncture points possible), minimal acupuncture (superficial needling of at least 6 of 10 predefined, bilateral, distant nonacupuncture points), or a waiting list control (2 months no acupuncture followed by semi-standardised acupuncture described above).

Outcome measures: Participating trial physicians and interventions.

Results: Forty-five (45) physicians specializing in acupuncture (mean age 44 ± 7.8 years, 23 (51%) female) in 30 outpatient centers in Germany provided the interventions. The median duration of acupuncture training of trial physicians was 350 hours (range 140–2508). The most frequently reported Chinese diagnosis was Kidney deficiency (39%), followed by *qi* and Blood stagnation (24%), and *bi* syndrome (20%). The total number of needles used was 17.3 ± 4.2 in the acupuncture group compared to 12.3 ± 1.2 in the minimal acupuncture group. In total, 40 physicians (89%) stated that they would have treated patients similarly or in exactly the same way outside of the trial, whereas 5 (11%) stated that they would have treated patients differently.

Conclusions: For most trial physicians, the semistandardized acupuncture strategy used in this trial was an acceptable compromise for an efficacy study. However, a relevant minority of participating trial physicians stated that they would have treated patients differently outside of the trial.

INTRODUCTION

In the last decade, an increasing number of randomized controlled trials examining the efficacy of acupuncture in

patients suffering from low-back pain have been published. However, the limited methodological quality of acupuncture trials and, in particular, insufficient descriptions of the study interventions have been criticized.^{1–3}

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In 2001, the STRICTA (Standards for Reporting Interventions in Controlled Trials of Acupuncture) recommendations were published to encourage more precise descriptions of the interventions used in controlled trials of acupuncture and to improve the quality of these interventions themselves.⁴ The recommendations emphasize the need to provide details on the rationale for the chosen acupuncture strategy, as well as for needling, treatment regimen, co-interventions, practitioner background, and control interventions.

In the randomized multicenter Acupuncture Randomized Trial (ART) on low-back pain (LBP), we investigated whether a semistandardized acupuncture intervention was more effective than standardized minimal acupuncture or no treatment in patients with chronic low-back pain. The ART LBP trial was part of two larger research programs developed upon the request of health care authorities in Germany and sponsored by a group of statutory health insurance funds.^{5,6} The goal of the program was to determine whether acupuncture should be reimbursed as part of standard medical care in Germany. The protocol and primary results have been published elsewhere.^{7,8}

The aim of this paper is to provide details on the characteristics and backgrounds of the acupuncturists who participated, and the trial interventions that were applied, in the ART LBP study.

METHODS

The ART LBP trial was a randomized, controlled multicenter trial comparing acupuncture with minimal acupuncture and with a no-acupuncture waiting list control. Patients with chronic low-back pain who fulfilled predefined inclusion criteria were centrally randomized (ratio 2:1:1) to one of the three treatment groups. In the acupuncture and minimal acupuncture groups, patients were blinded to treatment.

The participating physicians were recruited in a manner designed to ensure that their qualifications were at least equal to the average qualifications of physicians currently accredited by statutory health insurance funds in Germany to perform acupuncture treatment. According to the study protocol, trial physicians had to fulfill the following criteria: (1) acupuncture training at least equivalent to an A-diploma from one of the major German acupuncture societies (140 hours of acupuncture training); (2) 50% of trial physicians had to have at least a B-diploma (350 hours; approximately 20% of physicians accredited to provide acupuncture as part of current reimbursement programs outside the trials have this qualification);⁷ (3) 50% had to have experience working in clinical studies; (4) all physicians had to have at least 3 years of practical experience with acupuncture; and (5) all physicians were required to participate in study training sessions on the trial methods, the study interventions, and standards for performing clinical trials (International Conference on Harmonisation-Good Clinical Practice).⁹

We developed the treatment strategies for acupuncture and minimal acupuncture in a consensus process with three acupuncture specialists (D.I., J.H., M.H.) representing two major German societies for medical acupuncture: the German Medical Acupuncture Association (Deutsche Ärztegesellschaft für Akupunktur, DÄGfA) and the International Society for Chinese Medicine (Societas Medicinae Sinensis, SMS). The first step involved three specialists (D.I., J.H., M.H.) and the study team developing a proposal, which was followed by a discussion including more than 30 acupuncture experts from both acupuncture societies. The final intervention strategies were defined by the abovementioned three specialists together with the study team and subsequently were communicated to the external advisors.

Both the acupuncture and minimal acupuncture treatments consisted of 12 sessions of 30 minutes' duration administered during a period of 8 weeks (preferably 2 sessions

Minimal Acupuncture Points Used in the Acupuncture Randomized Trial on Low-Back Pain

1. MA-point **"Deltoideus"**: In the middle of the insertion line of M. deltoideus (LI 14) and Acromion.
2. MA-point **"Upper Arm"**: 2 *cun* laterally (radial) of LU 3.
3. MA-point **"Forearm"**: 1 *cun* ulnar of the proximal third of the line between Heart (HE) 3 and HE 7.
4. MA-point **"Scapula"**: 1 *cun* laterally of the lower scapular edge.
5. MA-point **"Spina Iliaca"**: 2 *cun* above spina iliaca anterior superior in vertical line to the arch of left ribs.
6. MA-point **"Back I"**: 5 *cun* laterally of the spine of lumbar vertebra IV.
7. MA-point **"Back II"**: 5 *cun* laterally of the spine of lumbar vertebra V.
8. MA-point **"Upper Leg I"**: 6 *cun* above the upper edge of the patella (between the spleen and stomach meridian).
9. MA-point **"Upper Leg II"**: 4 *cun* above the upper edge of the patella.
10. MA-point **"Upper Leg III"**: 2 *cun* dorsally of GB 31 (avoidance of bladder meridian).

One *cun* is defined according to the rules of Traditional Chinese Medicine as the width of the interphalangeal joint of the patient's thumb.

TABLE 1. CHARACTERISTICS OF PARTICIPATING TRIAL PHYSICIANS, AS WELL AS PHYSICIAN ASSESSMENT OF INTERVENTIONS

	<i>Mean, median (range) or n (%)</i>
Number of acupuncture sessions provided in the trial	74, 45 (3–291)
Age (years)	44, 43 (29–65)
Gender: female	23 (51%)
Postgraduate specialization (“ <i>Facharzt</i> ”)	29 (64%)
Number of years in medical practice	17, 17 (1–41)
B-diploma (at least 350 hours training)	33 (73%)
Hours acupuncture training	594, 350 (140–2508)
Teacher for acupuncture in accredited postgraduate courses	17 (38%)
Number of years you have used acupuncture (prior to beginning of study)	11, 10 (0–25)
Membership in professional societies	
Total	41 (91%)
German Medical Acupuncture Association (DÄGfA)	15 (33%)
International Society for Chinese Medicine (SMS)	12 (27%)
German Association for Acupuncture and Neuraltherapy (DGfAN)	5 (11%)
Research Association for Acupuncture (FATCM)	2 (4%)
Others	18 (40%)
Patients treated with acupuncture in the year before the trial	
Total	346, 300 (22–1200)
Low-back pain patients	153, 60 (5–1500)
Therapies used in patients in everyday practice (percentages)	
Acupuncture	40% (3–100%)
Other traditional Chinese therapies	19% (0–60%)
Other complementary therapies	13% (0–50%)
Conventional medicine	35% (0–95%)
Rarely/frequently/always Chinese diagnosis before treatment	4 (9%)/16 (36%)/25 (56%)
How would you have applied acupuncture outside of the trial?	
In exactly the same way	3 (7%)
Similarly	37 (82%)
Differently	5 (11%)
In an entirely different manner	0 (0%)
Would you have used additional therapies outside of the trial?	
No	4 (9%)
Yes, in some patients	34 (76%)
Yes, almost always	7 (16%)
Did you have problems with minimal acupuncture?	
Yes, on an ethical level	23 (51%)
Yes, technically	3 (7%)
Yes, during informed consent	21 (47%)

a week for the first 4 weeks, followed by 1 session per week for the remaining 4 weeks). Patients in the waiting list group did not receive acupuncture treatment during the first 8 weeks after randomization; as of week 9, they received the acupuncture treatment described below.

Acupuncture points were selected based on disease patterns and recommendations of Traditional Chinese Medicine (TCM), adapted to clinical experiences in Germany. The primary reasons for low-back pain according to TCM are stasis of *qi* and *xue* (blood), cold and damp-cold as an exogenous pathogenic factor (also called bi-syndrome), depletion of *qi*, *yang*, *xue*, or *yin*. Some of the disease patterns are referred to organs (orbes) defined by Chinese Medicine, such as Kidney, for example, Kidney *yang* depletion. Each pattern leads to a combination of acupuncture points, comprising mostly local plus distant points. Unfortunately, moxibustion—normally an essential part of treatment—was not

allowed because of the difficulties involved in blinding patients to this form of treatment.^{10,11} Syndrome diagnoses according to Chinese Medicine were defined and documented by the acupuncturists on a voluntary basis.^{12,13}

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 selections:¹⁴ BI 20–34, BI 50–54; Gb 30; GV 3, 4, 5, 6; Extraordinary points Huatuojiuji and Shiqizhuixia. Also, physicians selected and needled bilaterally a minimum of 2 distant points from the following sample: SI 3; BI 40, 60, or 62; Ki 3, 7; Gb 31, 34, 41; Li; 3 and GV 14 and 20. In the event of a local or pseudo-radicular sensation, at least 2 local points were added. Sterile, disposable one-time needles were used. Needle length and diameter were not predefined, but had to be documented. Physicians were instructed to achieve the

TABLE 2. SYNDROME DIAGNOSES ACCORDING TO TRADITIONAL CHINESE MEDICINE (TCM)

TCM Diagnosis in patients in the ART for LBP			n (%)	
Patients with TCM diagnosis			181 (60%)	
Patients with 1 TCM diagnosis			44 (15%)	
Patients with 2 TCM diagnoses			70 (23%)	
Patients with 3 TCM diagnoses			54 (18%)	
Patients with >3 TCM diagnoses			13 (4%)	
			TCM diagnosis 1 (N = 181)	TCM diagnoses (all) (N = 399)
Group	Subgroup	Syndrome diagnoses	n (%)	n (%)
I.		Bi syndrome (all)	36 (20%)	96 (24%)
	1	Bi syndrome ^a	10 (6%)	13 (3%)
	1a	Cold	13 (7%)	29 (7%)
	1b	Damp	9 (5%)	35 (9%)
	1c	Heat	3 (2%)	15 (4%)
	1d	Wind	1 (1%)	4 (1%)
II.		Qi and Blood stagnation (all)	43 (24%)	97 (24%)
	2	Qi and blood stagnation ^a	4 (2%)	7 (2%)
	3	Blood stagnation	20 (11%)	49 (12%)
	4	Qi stagnation (+ liver qi stagnation)	19 (10%)	41 (10%)
III.		Kidney deficiency (all)	71 (39%)	136 (34%)
	5	Kidney deficiency ^a	7 (4%)	18 (5%)
	6	Kidney yang deficiency ^b	29 (16%)	44 (11%)
	7	Kidney yin deficiency ^c	23 (13%)	47 (12%)
	8	Kidney qi deficiency	12 (7%)	27 (7%)
IV.		Liver and spleen qi deficiency (all)	16 (9%)	25 (6%)
	9	Liver qi deficiency	1 (<1%)	1 (<1%)
	10	Spleen qi deficiency	15 (8%)	24 (6%)
V.	11	Other diagnosis	15 (8%)	45 (11%)

^aGeneral category, more specific diagnosis was not mentioned.

^bYang deficiency was interpreted as Kidney yang deficiency.

^cYin deficiency was interpreted as Kidney yin deficiency. In case of damp Cold and Dampness Heat bi syndrome, the definitions "Cold" and "Heat bi syndrome" were used.

ART, Acupuncture Randomized Trial; LBP, low-back pain.

characteristic *de qi* needling sensation, if possible. Needles were to be stimulated manually at least once in each session.

The number, duration, and frequency of the sessions in the minimal acupuncture group were the same as for the acupuncture group. Minimal acupuncture treatment entailed superficially inserting fine needles (20–40 mm in length) at predefined, distant nonacupuncture points. These nonacupuncture points were not in the area of back pain and the selection of at least 6 out of 10 points was left to the physician's discretion (see box entitled Minimal Acupuncture Points Used in the Acupuncture Randomized Trial on Low-Back Pain). Physicians were instructed to avoid manual stimulation of the needles and provocation of *de qi* in the minimal acupuncture group. In investigator meetings, all acupuncturists received instructions on the application of minimal acupuncture, including a videotape and a brochure with detailed information on the intervention.

Patients were allowed to use oral nonsteroidal anti-inflammatory drugs, if required. The use of corticosteroids or

pain-relieving drugs that act through the central nervous system, however, were prohibited. Any concomitant pain medication had to be documented.

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."

We sent a questionnaire to all study physicians after study completion, but before informing them of the results of the study. This questionnaire included questions on physician training and experience prior to trial participation, as well as questions on how the trial interventions were judged posthoc.

RESULTS

A total of 301 patients (68% female, 59 ± 9 years) were randomized in the ART LBP study between March and Oc-

tober 2002. Five hospital outpatient units and 25 private practices participated as study centers. A total of 45 physicians applied acupuncture in the trial. The characteristics of the 45 physicians providing acupuncture are summarized in Table 1. The number of acupuncture treatments provided varied between 3 and 291 (median 45) per physician. Physicians had a median of 350 hours (range 140–2508 hours) of acupuncture training before participating in the trial; 33 (73%) had the B-Diploma. Seventeen (17; 38%) trial physicians taught acupuncture in accredited postgraduate courses. The physicians had used acupuncture in their practices for an average of 11 years (median 10, range 0–25) and had treated 346 patients (range 22–1200) with acupuncture in the year before the trial. Forty-one physicians (92%) indicated that they frequently or always make a Chinese syndrome diagnosis before starting treatment.

One or more Chinese syndrome diagnoses were recorded for 181 (60%) of the 298 patients (Table 2). Altogether, 399 Chinese syndrome diagnoses were made by the physicians. The most frequently reported Chinese diagnosis was Kidney deficiency (39%), followed by *qi* and Blood stagnation (24%), and Bi syndrome (20%).

Patients in the acupuncture group were treated in a total of 1622 sessions (Table 3). According to the protocol, all patients were treated with both local and distant points. On average, 17.3 ± 4.2 (mean and standard deviation) needles

were used per session, and the mean duration of each acupuncture session was 28.4 ± 3.2 minutes. The number of needles per session remained stable within each course of treatment. In most cases, the needle length was 21–30 mm. In almost all patients (>99%), it was possible to elicit the *de qi* sensation, and, in the most cases (65%), manual stimulation of the needles was performed at least once.

Additional classical points not mentioned as local or distant points in the treatment instructions were used in 34%, microsystem points in 12%, and trigger points in 13% of the sessions. In 60% of all sessions, the acupuncture was performed in the same manner as in the previous session.

The mean number of local needles was 9.6 ± 2.6 . The most frequently treated local points were BI 23, BI 25, Gb 30, DU 4, BI 26, and the extra point Huatuojiagi (Table 4). The mean number of distant points was 5.9 ± 2.2 . The most frequently treated distant points were BI 40, Kid 3, Gb 34, BI 60, SI 3, and DU 20. In most cases, 8 to 12 local points and 4 to 6 distant points were used. Physicians used additional acupuncture points in 565 of the treatment sessions. The most frequently used additional local points were Li 4, St 40, BI 17, Sp 6, and St 36.

Patients in the minimal acupuncture group were treated in a total of 835 sessions (Table 5). In most cases, the needle length was 21–30 mm. The most frequently used minimal acupuncture points were “Back 2,” “Back 1,” “Upper

TABLE 3. TREATMENT IN THE ACUPUNCTURE GROUP

	All sessions n = 1662 %/x ± SD	Session 1 n = 144 %/x ± SD	Session 5 n = 142 %/x ± SD	Session 10 n = 134 %/x ± SD
Total number of needles	17.3 ± 4.2	16.6 ± 4.1	17.6 ± 4.2	17.4 ± 4.6
Duration of session (min)	28.4 ± 3.2	28.1 ± 3.3	28.5 ± 3.4	28.4 ± 3.0
Additional points used in case of pseudoradicular radiating sensation	9%	8%	9%	8%
In case of pseudoradicular radiating sensation: number of needles	2.3 ± 1.6	2.9 ± 2.3	2.1 ± 0.8	2.1 ± 0.7
Other classic acupuncture points used	34%	24%	32%	43%
Other classical acupuncture points: number of needles	2.7 ± 1.7	2.5 ± 2.2	2.6 ± 1.6	2.6 ± 1.6
Trigger points used	13%	10%	11%	15%
Trigger points: number of needles	2.2 ± 1.1	1.9 ± 1.2	2.1 ± 1.1	2.0 ± 1.0
Microsystem points used	12%	9%	13%	10%
Microsystem points: number of needles	4.3 ± 2.2	4.6 ± 2.3	4.7 ± 2.2	4.4 ± 2.1
Acupuncture used as before	60%	—	61%	72%
Length of needles used				
<20 mm	26%	21%	29%	28%
21–30 mm	70%	72%	70%	68%
31–40 mm	61%	60%	61%	59%
>40 mm	32%	34%	35%	32%
Manual stimulation				
None	17%	20%	16%	22%
Once	65%	63%	67%	60%
More than once	18%	17%	17%	18%
<i>De qi</i>				
Easy to elicit	87%	71%	87%	93%
Difficult to elicit	13%	27%	13%	7%
Could not be elicited	0.2%	2%	0%	0%

TABLE 4. LOCAL AND DISTANT POINTS IN THE ACUPUNCTURE GROUP

	<i>All sessions</i> n = 1662 %/x ± SD	<i>Session 1</i> n = 144 %/x ± SD	<i>Session 5</i> n = 142 %/x ± SD	<i>Session 10</i> n = 134 %/x ± SD
Local point BI 23	72%	77%	72%	72%
Local point BI 24	36%	38%	36%	36%
Local point BI 25	69%	69%	68%	69%
Local point BI 26	32%	30%	31%	31%
Local point BI 28	26%	26%	27%	28%
Local point BI 54	23%	26%	20%	22%
Local point Gb 30	32%	29%	31%	34%
Local point DU 3	26%	28%	26%	28%
Local point DU 4	28%	34%	32%	25%
Extra Point Huatuoji	28%	22%	28%	28%
Local points: number of needles	9.6 ± 2.6	9.5 ± 2.6	9.6 ± 2.6	9.5 ± 2.5
Local points used				
<8 (4 × 2)	11%	15%	10%	11%
8–12 (4 × 2 bis 6 × 2)	77%	74%	80%	75%
13–16 (7 × 2 bis 8 × 2)	9%	10%	7%	11%
>16 (>8 × 2)	3%	2%	3%	2%
Distant point SI 3	34%	38%	32%	32%
Distant point BI 40	56%	59%	56%	54%
Distant point BI 60	43%	44%	46%	44%
Distant point BI 62	19%	21%	20%	17%
Distant point Kid 3	47%	49%	45%	45%
Distant point Gb 31	9%	8%	9%	11%
Distant point Gb 34	45%	41%	48%	48%
Distant point Gb 41	8%	7%	6%	10%
Distant point Liv 3	19%	15%	16%	22%
Distant point DU 20	24%	21%	25%	24%
Distant points: number of needles	5.9 ± 2.2	5.7 ± 2.1	5.9 ± 2.2	6.1 ± 2.2
Distant points used				
<4 (2 × 2)	9%	10%	8%	10%
4–6 (2 × 2 or 2 × 3)	59%	58%	58%	59%
7–8 (2 × 4)	22%	24%	22%	19%
>8 (2 × 4)	11%	9%	12%	12%

Thigh III,” “Scapula,” and “Deltoideus,” all of which were used in more than 70% of the cases.

Posthoc physician assessment of the trial interventions are summarized in Table 1. Forty (40) physicians (89%) reported that they would have applied acupuncture similarly, or in exactly the same way, outside of the trial. Five (5) physicians (11%) stated that they would have treated patients differently. However, the majority of physicians (76%) indicated that they would have used additional therapies outside of the trial, at least for some patients. When asked in these cases which additional therapies they would have used, physicians mentioned a great variety of treatments, including Chinese herbs, homeopathy, relaxation, and nutritional changes. About half of the physicians (51%) believed that providing minimal acupuncture was problematic from an ethical point of view. However, from a technical standpoint, the majority of physicians (93%) had no difficulties performing the specified minimal acupuncture technique, and all acupuncturists stated that they had performed the minimal acupuncture according to the treatment protocol. Thirty-seven (37; 82%) physicians explicitly con-

firmed that, were another such trial to be conducted, they would participate again. However, 7 (16%) indicated that they would not participate again (1 answer missing). In the latter 7 cases, physicians gave the following reasons for their answer: the use of minimal acupuncture, the lack of complete individualization, and the amount of “bureaucracy” involved in the trial.

DISCUSSION

In the present study, physicians who participated in the ART LBP were a heterogeneous group whose overall qualifications were higher (at least 350 hours training: 73%) than the average qualifications of physicians who provide acupuncture within the German system of statutory reimbursement (at least 350 hours training: 22%).¹⁵ In addition, our data indicate that the consensus-based treatment protocol used for acupuncture and minimal acupuncture in this trial was a feasible approach that found acceptance among participating physicians. Nevertheless, it should be noted

that approximately 15% of the trial physicians would have applied acupuncture differently outside of the study, and most would have used additional therapies if they had been given the choice. In addition, almost none of the acupuncturists had technical difficulties performing the minimal acupuncture treatment; however, approximately half of them indicated that they found it difficult to inform patients about minimal acupuncture and that they found minimal acupuncture itself to be ethically problematic.

Defining study interventions in clinical trials of acupuncture is a difficult task. An ideal acupuncture intervention should be acceptable to acupuncture experts, representative of common practice, and should be reproducible.¹⁶ However, there are relevant variations in the treatment of chronic low-back pain in common practice.^{17,18} This variation is partly because of the existence of different schools of acupuncture and partly because of individualization. According to the diagnostic framework of TCM, chronic low-back pain cannot be considered a single disease entity. Different patients may have different diagnostic patterns and, therefore, need different treatment. In addition, acupuncturists are normally permitted to use additional techniques, such as cupping or moxibustion in some patients.¹⁸

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 a suitable one. Nevertheless, it is, of course, impossible to predict whether our findings would have been different if another acupuncture strategy had been used. In addition, it is likely that the selection of participating trial acupuncturists had an effect on the results of the study. Thus, it is important to emphasize that this study, like all other

acupuncture studies, does not investigate the effectiveness of acupuncture in general, but rather the effectiveness of a specific acupuncture intervention.

The fact that three points (Bl 23, Bl 25, and Bl 40) were chosen in more than 50% of all sessions demonstrates their key role, which is reflected in the literature on Chinese classical acupuncture.¹⁹ A great variety of additional points was applied, reflecting a partially individualized treatment scheme. It is not surprising that the most frequently used local and distant acupuncture points were in good accordance with points described in other surveys and studies.^{16–18} There are still some differences in general practice, however. For example, in one survey of acupuncturists, the use of *Ashi* points was much higher than in our trial.¹⁶ However, in most studies on acupuncture treatment in low back pain, *Ashi* was—as in our study—a minor treatment option.^{17,18}

According to the rules of Traditional Chinese Medicine (TCM), it is essential to define a Chinese syndrome diagnosis for each patient individually before starting treatment. In our study, the most frequently reported Chinese diagnosis was Kidney deficiency, followed by *qi* and Blood stagnation, and *bi* syndrome. These diagnoses were in accordance with an analysis of TCM acupuncture texts, which, for the most part, describe three or four diagnosis patterns and could be categorized roughly into the three types mentioned above.²¹ The abovementioned syndrome patterns are diagnosed frequently in patients suffering from LBR.^{16,17,21} Compared to the syndrome analyses described in another trial,²¹ the diagnoses of Kidney deficiency and *bi* syndrome were distributed evenly in our study population. However, the diagnoses *qi* and Blood stagnation occurred more frequently in the abovementioned trial than in our trial. This

TABLE 5. TREATMENT IN THE MINIMAL ACUPUNCTURE GROUP

	All sessions (n = 835) %/x ± SD	Session 1 (n = 71) %/x ± SD	Session 5 (n = 71) %/x ± SD	Session 10 (n = 68) %/x ± SD
Point "Deltoideus"	71%	75%	68%	72%
Point "Upper Arm"	49%	51%	48%	47%
Point "Lower Arm"	37%	38%	37%	40%
Point "Scapula"	75%	70%	75%	75%
Point "Back I"	93%	94%	93%	93%
Point "Back II"	96%	97%	96%	96%
Point "Spina iliaca"	37%	37%	38%	35%
Point "Upper Thigh I"	38%	35%	41%	37%
Point "Upper Thigh II"	31%	32%	34%	29%
Point "Upper Thigh III"	86%	85%	87%	85%
Total number of needles	12.3 ± 1.2	12.3 ± 1.2	12.3 ± 1.2	12.2 ± 1.0
Length of needles used				
<20 mm	34%	34%	34%	32%
21–30 mm	49%	49%	51%	52%
31–40 mm	28%	28%	27%	25%
>40 mm	2%	1%	1%	2%
Duration of sessions (minutes)	28.5 ± 3.0	28.4 ± 3.0	28.6 ± 2.8	28.4 ± 3.2

could possibly be explained by the different view on pain in the various schools of Chinese medical thought. Some schools routinely describe pain as a form of *qi* and Blood stagnation, whereas other schools focus more on the underlying reasons for pain.

Even more difficult than defining the acupuncture intervention is the choice of an appropriate sham control. The German health authorities requested that our trial include a “sham” or “placebo” condition to investigate whether the effects of acupuncture are specific. However, the concepts of “placebo” and “specific effects” are unclear in the context of acupuncture.²² Although there can be little doubt that locating points correctly should matter, other aspects, such as skin penetration, depth of needling, and manipulation of needles, may be relevant effect modifiers. In the absence of an inert and indistinguishable placebo, a wide variety of sham interventions have been used in acupuncture trials. Based on a systematic review of such interventions,²³ as well as on our consensus process with acupuncture experts, we decided to use a minimal acupuncture intervention²⁴ as a sham control. It differed from the full or true acupuncture intervention with regard to point location, needling depth, and the avoidance of *De qi* and manual needle stimulation. Similar interventions have been used in a variety of previously published trials.²³

CONCLUSIONS

In conclusion, we believe that the treatment protocols for semistandardized acupuncture and standardized minimal acupuncture in the ART LBP trial represent an acceptable compromise, especially in light of the study’s specific purpose.

TRIAL REGISTRATION NUMBER

This trial was not registered; however, the protocol of the trial was prepublished.⁷

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