

Acupuncture for Upper-Extremity Rehabilitation in Chronic Stroke: A Randomized Sham-Controlled Study

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ABSTRACT. Wayne PM, Krebs DE, Macklin EA, Schnyer R, Kaptchuk TJ, Parker SW, Scarborough DM, McGibbon CA, Schaechter JD, Stein J, Stason WB. Acupuncture for upper-extremity rehabilitation in chronic stroke: a randomized sham-controlled study. *Arch Phys Med Rehabil* 2005;86:2248-55.

Objective: To compare the effects of traditional Chinese acupuncture with sham acupuncture on upper-extremity (UE) function and quality of life (QOL) in patients with chronic hemiparesis from stroke.

Design: A prospective, sham-controlled, randomized controlled trial (RCT).

Setting: Patients recruited through a hospital stroke rehabilitation program.

Participants: Thirty-three subjects who incurred a stroke 0.8 to 24 years previously and had moderate to severe UE functional impairment.

Interventions: Active acupuncture tailored to traditional Chinese medicine diagnoses, including electroacupuncture, or sham acupuncture. Up to 20 treatment sessions (mean, 16.9) over a mean of 10.5 weeks.

Main Outcome Measures: UE motor function, spasticity, grip strength, range of motion (ROM), activities of daily living, QOL, and mood. All outcomes were measured at baseline and after treatment.

Results: Intention-to-treat (ITT) analyses found no statistically significant differences in outcomes between active and sham acupuncture groups. Analyses of protocol-compliant subjects revealed significant improvement in wrist spasticity ($P < .01$) and both wrist ($P < .01$) and shoulder ($P < .01$) ROM in the active acupuncture group, and improvement trends in UE motor function ($P = .09$) and digit ROM ($P = .06$).

Conclusions: Based on ITT analyses, we conclude that acupuncture does not improve UE function or QOL in patients with chronic stroke symptoms. However, gains in UE function

observed in protocol-compliant subjects suggest traditional Chinese acupuncture may help patients with chronic stroke symptoms. These results must be interpreted cautiously because of small sample sizes and multiple, unadjusted, post hoc comparisons. A larger, more definitive RCT using a similar design is feasible and warranted.

Key Words: Acupuncture therapy; Cerebrovascular accident; Hemiparesis; Muscle spasticity; Range of motion, articular; Rehabilitation.

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ACUPUNCTURE HAS BEEN PRACTICED in China for more than 3000 years, and in recent years has become increasingly integrated into mainstream biomedicine.¹ Recent surveys suggest acupuncture is commonly used after stroke in China today and in the treatment of other neurologic disorders.^{2,3} Recent systematic reviews,⁴⁻⁶ including a 1997 National Institutes of Health consensus statement,⁷ suggest that acupuncture may be a useful adjunct to stroke rehabilitation, but caution that stronger conclusions are limited by inappropriate designs, small samples size, and lack of appropriate controls. A recent meta-analysis⁸ of randomized controlled trials (RCTs) that evaluated the benefits of acupuncture administered during the acute stage of recovery from stroke concluded that when added to standard stroke rehabilitation, acupuncture has no effect on motor recovery but may have an improved effect on disability.

Data about the benefits of acupuncture in long-term stroke survivors with chronic symptoms are more limited. Studies conducted in China suggest acupuncture can improve motor function and activities of daily living (ADLs) when administered during the subacute and chronic stages of stroke recovery, but that the magnitude of improvement is generally not as great as when the treatment is administered during the acute stage of recovery.⁹⁻¹¹ Naeser et al¹² reported in a case series improvement in hand dexterity and grip strength after acupuncture in 8 chronic stroke patients. In a second study,¹³ they reported improved knee flexion, knee extension, and shoulder abduction in chronic stroke patients after acupuncture, but only if pathology affected less than 50% of the motor pathways as revealed by computerized tomography scans. Neither study included a sham acupuncture control group.

Two aspects of the design of RCTs for evaluating the efficacy of acupuncture in stroke patients limit the conclusions that can be drawn from published research. First, the interventions used in control groups varied widely. Early RCTs compared the benefits of acupuncture plus standard care with standard care alone and reported that the addition of acupuncture improved the rate and magnitude of recovery.¹⁴⁻¹⁶ However, these studies potentially confound the specific effects of acupuncture needling with nonspecific effects of attention and expectation.^{17,18} More recent RCTs have used high frequency, low

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intensity, transcutaneous electronic nerve stimulation,¹⁷ or needles inserted shallowly at traditional acupoints¹⁹ as controls. Because the mechanisms underlying acupuncture are still poorly understood, particularly how acupuncture might benefit recovery from hemiparesis, it is unclear whether these “sham” treatments are truly inert.²⁰⁻²²

A second limiting aspect of studies of acupuncture in stroke patients is that many have used standardized acupuncture points in all subjects.^{17,19,23} The use of fixed, standardized prescriptions for acupuncture points deviates from traditional Chinese medicine (TCM) theory, which postulates that stroke survivors comprised a diversity of TCM diagnostic classes, each with different stroke etiologies and symptoms.²⁴⁻²⁶ Accordingly, TCM proposes that optimal treatment should use a unique acupuncture protocol for each diagnostic class. Therefore, studies that have used standardized treatments may not have effectively tested the benefits of acupuncture as it is clinically practiced.^{27,28} To evaluate the benefits of acupuncture for chronic stroke symptoms, and to address important methodologic issues, we compared the efficacy of an active, individualized, TCM-based protocol with a sham protocol in which a validated sham acupuncture needle device was used.²⁹⁻³¹ Our study was designed to collect data with which to assess whether active acupuncture improves upper-extremity (UE) range of motion (ROM), spasticity, and motor function; and to assess whether active acupuncture improves ADLs, quality of life (QOL), and mood.

METHODS

Study Design

This study was a 2-arm RCT with blinding of patients and assessors, but not acupuncturists. Patient recruitment was coordinated through Spaulding Rehabilitation Hospital's Stroke Service and targeted people in the greater Boston area. Recruitment included use of hospital databases; letters to local hospital neurologists, nursing homes, and stroke support group leaders; and newspaper advertising.

To be eligible, patients were required to have moderate UE dysfunction from a first stroke incurred at least 6 months earlier. Moderate UE dysfunction was defined as at least some weakness or functional limitation, but not so severe as to prevent a patient from being able to raise the impaired arm from a hanging position to a tabletop while seated (knees 15.2 cm [6in] under table). Other inclusion criteria were the ability to arise independently from a chair and the ability to walk independently with or without a cane or walker. Exclusion criteria were: (1) previous experience with acupuncture; (2) contraindications to electroacupuncture, including wearing of pacemakers or embedded neural stimulators, cardiac arrhythmia, epilepsy, or women who were pregnant or trying to conceive^{32,33}; (3) comorbidities that would prohibit participation in study procedures, including active renal dialysis, metastatic cancer, or extremity fracture within the past 6 months; (4) simultaneous participation in other forms of physical or occupational therapy; (5) enrollment in other studies that involved active interventions; or (6) cognitive impairment that would interfere with one's ability to give informed consent. Two independent institutional review boards approved the study.

Study Procedures

Patients deemed eligible from an initial phone screening were scheduled for an enrollment interview at the New England School of Acupuncture, during which the study's objec-

tives and procedures were explained. Eligible subjects who agreed to participate provided written informed consent according to institutional guidelines on human research and were randomly assigned to either an active acupuncture or a sham acupuncture group. To ensure an equal proportion of severely impaired patients in each study arm, randomization was stratified by the severity of the patients' hand motor impairment as assessed by their ability to tap the index finger of the impaired hand 3 or more times on a tabletop within 15 seconds. Computer-generated randomization within each stratum was conducted using permuted blocks of 4, with consecutively numbered sealed opaque envelopes for each group prepared by the study's statistician. The study's principal investigator (PMW) opened the envelopes consecutively after each patient's enrollment and informed the acupuncturist as to which treatment group the patient was assigned.

Patients, study staff, and outcome assessors were blinded to treatment group assignment. The success of patient blinding was assessed after the second and 20th (final) acupuncture treatments with a self-administered instrument (modified from Kalish et al³⁴). To do this, subjects were asked to indicate the treatment group to which they believed they were assigned by circling the applicable statement: (1) I believe I am in the active acupuncture group; (2) I believe I am in the inactive, sham acupuncture group; or (3) I am unsure what group I am in. If they chose response (1) or (2), they were also asked to rate how confident they were of their answers on a 5-point Likert scale.

Interventions

Both the active and sham acupuncture protocols were developed using an expert panel consensus process (R.N. Schnyer et al, unpublished data, 2005). Treatments were administered twice weekly for 10 weeks by 2 licensed TCM-style acupuncturists who were trained in China and had an average of 20 years of clinical experience treating stroke patients in China and the United States.

Active acupuncture intervention. We followed a flexible, yet standardized and replicable, protocol using the manualization process used in other acupuncture RCTs.^{34,35} The protocol was based on TCM-style acupuncture^{36,37} and consisted of a combination of traditional acupuncture points on the body surface and a modern system of “scalp” acupuncture.³⁸ Both manual and electrostimulation were applied to the body points, while manual stimulation only was applied to the scalp points. Body and scalp acupuncture protocols were alternated on a weekly basis.

All patients received a TCM evaluation at each visit based on the “4 examinations”: interrogation, looking, smelling and listening, and palpation.¹ These evaluations determined the specific acupuncture points and stimulation strategies to be applied during the visit.

Specific body acupuncture points used are listed in appendix 1. Manual stimulation was applied on body parts until a characteristic response referred to as *de qi* was obtained. *De qi* has a sensory component perceived by the patient as a heaviness or ache in the tissue surrounding the needle, and a biomechanical component perceived by the practitioner as a needle grasp.³⁹ Additionally, electric stimulation^a was applied to points on the affected limbs. Scalp acupuncture was directed at sensory and motor components of the affected limb.^{14,38} A total of 2 to 3 acupuncture scalp lines were selected per session (5–7 needles in total). Needling was performed on the side opposite the affected limb, and thus, on the side of the stroke. For both body and scalp treatments, needles were left in place for 20 to 30 minutes. Each session lasted approximately 60 minutes. We

used stainless steel disposable, presterilized needles (34 gauge; length, 30–40mm) for all active treatments.

Sham acupuncture intervention. For the sham acupuncture, we used a sham acupuncture needle developed by Streitberger and Kleinhenz²⁹ and validated in various populations,^{30,31} including stroke patients.^{40,41} The device works like a magician's sword: the patient sees and feels the acupuncture needle, but as it is applied to the skin, the needle retracts and slides up the needle shaft rather than penetrating the skin. For body points, a 1 cm-diameter plastic ring, covered and held in place with paper surgical tape, supported needles in a vertical position. At each body treatment visit, 4 to 6 sham needles were placed at predetermined locations at least 1cm away from any acupuncture point (Schnyer, unpublished data). One to 2 needles were located on each affected arm and leg. In addition, 1 needle each was placed on both the healthy arm and leg. Sham electroacupuncture was administered to arm needles, using wires that were severed and retaped so as to leave a gap, and thus not conduct electricity. We also used sham needles for the sham scalp acupuncture. Two sham needles were located 2cm from active scalp lines.

To further reduce the chance that patients in the sham group would correctly guess their treatment group assignment, 1 real needle was administered in a visible location adjacent to Ren 6, on the abdomen without the use of a sham ring and tape. In addition, to avoid unblinding resulting from patients in different groups comparing their experiences, rings and tape were used on 1 needle in the active group at every session. Patients were told that the tape and rings were used on some points to ensure accuracy. Finally, to minimize nonspecific differences between active and sham protocols, we developed a standard operating procedure that was in all practitioner-patient interactions.

Outcome Assessments

The following outcomes were assessed at baseline and at a 12-week follow-up visit at the MGH Biomotion Laboratory.

UE function. Motor function was assessed using the UE motor component of the Fugl-Meyer Assessment (FMA; scale range, 0–66; normative score, 66).^{42–45} We used the Modified Ashworth Scale⁴⁶ to assess wrists and elbows while patients were seated. This well-validated instrument characterizes spasticity on a scale ranging from 0 (no increase in tone) to 4 (limb rigid in flexion or extension). Grip strength was assessed with a Jamar dynamometer.^b While seated, subjects performed the “three jaw chuck”¹² by pinching the tips of their first and second fingers against the dynamometer as hard as possible for 3 seconds with their thumbs positioned just beneath; the other hand was rested on the thigh. Subjects performed 1 practice trial before 2 measures were recorded, with a 60-second rest between trials. Recorded measures were averaged. Active-assisted UE ROM was tested while subjects were seated. The physical therapist assessed joint ROM by assisting the motion of each major UE joint through the full available motion and recording the maximum ROM values (angle values recorded in degrees).

ADLs, medical QOL, mood, expectation, and patient-practitioner interactions. ADLs were assessed with the Barthel Index (scale range, 0–20; score 20, greatest independence in ADLs).⁴⁷ Mood was assessed with the Center for Epidemiological Surveys Depression (CES-D scale) (scale range, 0–60; scores ≥ 16 indicated depression).⁴⁸ Health-related QOL (HRQOL) was assessed by using part I of the Nottingham Health Profile (NHP) along 6 dimensions: emotional relations, sleep, lack of energy, pain, physical mobility, and social isolation,⁴⁹ and scored by the method of O'Brien et al⁵⁰ (scale

range, 0–100; score 100, good QOL). Each of the above measures was administered at baseline and at 12-week and 6-month follow-up visits.

Patients' beliefs or expectations regarding the efficacy of acupuncture for treating stroke were assessed using a self-administered Treatment Credibility Scale (scale range, 0–4; score 4, greatest expectancy) developed by Borkovec and Nau,⁵¹ and modified for acupuncture studies.^{20,34,52} The instrument was administered at the baseline visit.

Patient-practitioner interactions were characterized by responses (scale range, 0–4; score 4, most satisfied) to 2 questions on a 5-point Likert scale: (1) “How dedicated do you think your acupuncturist is to helping you with your stroke symptoms?” and (2) “Has your acupuncturist treated you in a professional manner?” These questions were asked after the second acupuncture treatment.

Data Analysis

We used the Student *t* test and Fisher exact test to compare baseline characteristics of the 2 groups. Efficacy of acupuncture was tested for measures of FMA, spasticity, grip strength, ROM, ADLs, and QOL, and mood in multiple linear regression models, controlling for each measure at baseline, subject dexterity, baseline FMA score, and log-transformed time since stroke. Baseline values were included as covariates to control for regression to the mean. Dexterity, baseline FMA, and time since stroke were included based on an assumption of their expected clinical associations with outcomes, independent of treatment type. Age, sex, and acupuncturist were considered as covariates and were dropped. While more parsimonious models were adequate for some measurements, the full model was applied uniformly to all measurements to avoid overtailoring specific models to particular patterns in this small data set. Two sets of analyses were performed for all measurements. One set was an intent-to-treat (ITT) analysis that included all randomized subjects classified according to their randomization and irrespective of their completion of acupuncture or sham treatments. The second set was a per-protocol analysis that included only subjects who met the following criteria: baseline data collected before the start of treatment, 20 acupuncture or sham treatments completed in no more than 12 weeks, and follow-up data collected from 9 to 18 weeks after baseline. Results are reported as significant on a comparison-wise basis at α equal to .05 for 2-tailed tests.

RESULTS

Recruitment, Enrollment, and Protocol Adherence

Figure 1 summarizes the flow of subjects through the trial. Between October 1, 2002, and October 31, 2003, 140 stroke patients expressed interest in participating in the study. Ninety-three patients were ineligible because of: complete inability to move their arm (n=18) or no arm weakness (n=4); contraindications to electroacupuncture (n=14); prior acupuncture experience (n=23); currently enrolled in other studies or receiving other treatments (n=7); more than 1 stroke (n=4); less than 6 months poststroke (n=1); and recently fractured paretic arm (n=1). Eleven subjects were not interested and 14 decided not to participate because of transportation problems. The 33 patients who expressed interest and met the entry criteria provided written consent and were randomized to active (n=16) or sham (n=17) acupuncture. Dropouts and adherence to protocols are summarized in figure 1.

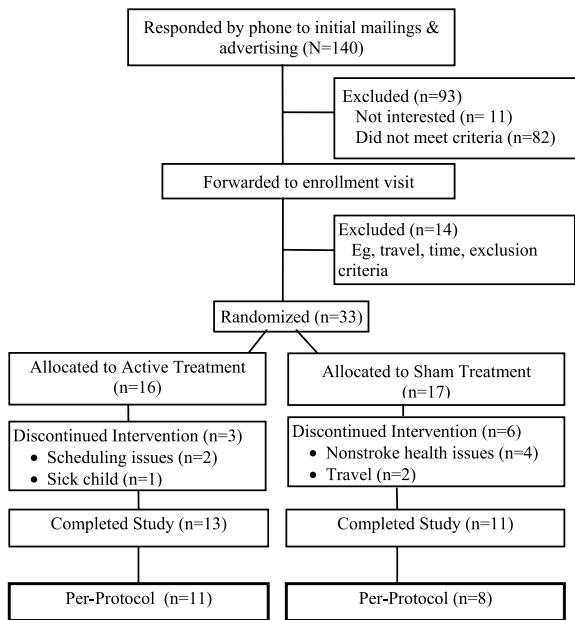


Fig 1. Flow diagram of subject progress through the trial.

Baseline Characteristics of Subjects

Baseline characteristics of our randomized subjects are summarized in table 1. Treatment assignments effectively randomized subjects on all parameters. Per-protocol patients did not differ from all randomized patients with respect to any baseline characteristics ($P \geq .14$).

Treatment Blinding

Masking of treatment assignment was effective (table 2). After 2 treatment sessions, 47% of subjects in the active group

and 64% in the sham group indicated they were not certain whether they were receiving active or sham therapy. Only 28% correctly guessed their assignment. Responses to the masking questionnaire did not differ by actual treatment assignment (Fisher exact test, $P = .71$). After completing all treatments, only 35% of subjects who completed the instrument correctly guessed their true assignment, and again, responses did not differ by treatment assignment (Fisher exact test, $P = .32$).

Efficacy of Acupuncture on UE Motor Function, Spasticity, and ROM

In the ITT analyses, no UE function measure differed significantly between 2 treatment groups after controlling for baseline values of each measure, baseline FMA, dexterity, and log-transformed time since stroke (table 3). In the per-protocol analyses, however, several 12-week change measures favored the active treatment group, including Ashworth wrist scores ($P < .01$); shoulder ROM through the frontal plane ($P < .01$); and wrist ROM in the sagittal and frontal planes ($P < .01$) (see table 3, fig 2). FMA ($P < .09$) and digit ROM ($P < .06$) showed trends toward improvements in the per-protocol active group relative to the sham group.

Efficacy of Acupuncture on ADLs, QOL, Mood, and Expectancy

In the ITT analyses, Barthel ADLs, NHP, and CES-D did not differ significantly between treatment groups at 12 weeks after controlling for baseline values of each measure, baseline FMA, dexterity, and log-transformed time since stroke (table 4). In the per-protocol analyses, the overall NHP scores improved more after 12 weeks in the sham group, which implies greater improvement in health perspectives among sham subjects. However, this was due largely to lower scores among sham subjects for the energy level dimension at baseline, rather than higher scores at 12 weeks. The median change was zero for all other NHP dimensions for both sham and active subjects. NHP

Table 1: Baseline Characteristics of Randomized Subjects

Characteristics	All (N=33)	Active (n=16)	Sham (n=17)	P
Age (y)	59 (28–89)	63 (28–89)	54 (42–69)	0.09
Sex (% male)	73	75	71	1.00
Race (% white)	78	75	76	1.00
Time since stroke (mo)	53 (10–292)	66 (12–292)	41 (10–123)	0.18
Dexterity (% high)	52	44	59	0.49
Barthel Index		95	97	0.62
NHP		86	87	0.54
CES-D		5.8	5.1	0.48
FMA		31	36	0.76
Three jaw chuck		6.1	7.7	0.31
Ashworth: elbow		1.7	2.3	0.18
Ashworth: wrist		1.6	1.8	0.54
ROM shoulder				
Sagittal plane		123	131	0.74
Frontal plane		143	149	0.64
Transverse plane		85	95	0.67
ROM elbow: sagittal plane		119	105	0.17
ROM forearm: transverse plane		140	138	0.48
ROM wrist				
Sagittal plane		91	83	0.54
Frontal plane		40	37	0.82
ROM thumb		48	52	0.99
ROM digits		58	63	0.97

NOTE. Values are mean (range) or percentage or as otherwise indicated.

Table 2: Masking of Treatment Group Assignments

Assessment	Group Assigned	n	Group Guessed, % (n)			P
			Active	Sham	Not Sure	
2-wk	Active	15	47 (7)	7 (1)	47 (7)	.71
	Sham	14	29 (4)	7 (1)	64 (9)	
3-mo	Active	13	46 (6)	38 (5)	15 (2)	.32
	Sham	10	30 (3)	20 (2)	50 (5)	

scores at 6-month follow-up differed between sham and active subjects along the energy level dimension due to the same difference at baseline, but none of the other dimensions or the overall score differed significantly.

Scores from the Treatment Credibility Scale showed that all subjects indicated high and equal levels of expectancy that acupuncture might be effective in treating stroke (median of 12 on a 3 to 15 scale for both groups), and were also generally satisfied with the professionalism and dedication of their practitioners (median of 5 on 1 to 5 scales for both measures in both groups).

DISCUSSION

The large number of stroke survivors with persistent UE dysfunction and associated disabilities has driven the search for novel interventions for rehabilitation.⁵³ Recently introduced approaches including constraint-induced movement therapy,^{54,55} computer-aided movement tracking,^{56,57} robot-aided training,⁵⁸⁻⁶⁰ and neuromuscular stimulation⁶¹ show promise but have not been consistently effective.

Our study is the first randomized, sham-controlled trial to evaluate the benefits of acupuncture for UE function and QOL in stroke survivors with persistent symptoms. ITT analysis found no significant differences in responses to treatment between subjects receiving active versus sham acupuncture for measures of arm function, ADLs, HRQOL, or mood. Two factors, however, caution against rejecting acupuncture as a therapy for chronic stroke based on these results. First, sample

sizes were small and confidence intervals for most measures were quite wide and included clinically relevant magnitudes of benefit from active acupuncture. Second, in the subset of subjects treated according to protocol specifications, active acupuncture significantly improved UE spasticity and ROM and showed trends toward improvement in motor function compared with the sham control, as we had hypothesized. It is possible, however, that these results were due solely to chance, given the large numbers of outcomes analyzed.

The results of 2 prior non-sham-controlled studies support the value of acupuncture in stroke survivors with disabilities in arm function. One study¹² reported improved hand dexterity and shoulder abduction, and the other¹³ showed significant increases in grip strength (three jaw chuck). Subjects in both studies had strokes 6 months to 8 years previously.

Especially noteworthy in our results were the clinically relevant observed changes in spasticity. A recent study⁶² reported spasticity in 19% of patients at 12 weeks post-stroke, and that spasticity was associated with significant deficits and disabilities. In our study, Ashworth scores of per-protocol subjects who received active acupuncture improved an average of 1.27 and 1.05 relative to sham subjects for the elbow and wrist, respectively, after controlling for important covariates. These improvements are comparable to changes in UE spasticity in chronic stroke patients after other therapies, such as botulinum toxin injections.⁶³ A recent RCT that evaluated acupuncture for chronic post-stroke leg spasticity reported no differences between active

Table 3: Efficacy of Acupuncture on UE Motor Function, Spasticity, and ROM After 12 Weeks

Measure	ITT				Per-Protocol			
	Adj R^2 (%)	Effect*	95% CI	P^{\dagger}	Adj R^2 (%)	Effect*	95% CI	P^{\dagger}
FMA	-13.3	-0.05	-4.2 to 4.1	.98	49.5	3.12	-0.6 to 6.9	.09
Ashworth: elbow	5.7	-0.20	-1.4 to 1.0	.74	29.1	-1.05	-2.6 to 0.5	.16
Ashworth: wrist	33.9	-0.57	-1.5 to 0.4	.22	62.3	-1.27	-2.2 to -0.3	.01*
Three jaw chuck	5.7	-2.22	-6.2 to 1.7	.25	-6.2	-0.5	-7.3 to 6.3	.87
ROM								
ROM shoulder								
Sagittal plane	43.5	1.70	-26.9 to 30.3	.90	47.2	22.59	-12.6 to 57.8	.18
Frontal plane	28.0	20.71	-12.0 to 53.5	.20	57.7	49.40	-13.5 to 85.3	.01*
Transverse plane	19.6	19.65	-4.3 to 43.6	.10	-6.9	24.79	-16.0 to 65.6	.20
ROM elbow: sagittal plane	71.1	-1.46	-17.0 to 14.1	.85	80.9	9.10	-12.5 to 30.7	.36
ROM forearm: transverse plane	13.1	6.25	-45.0 to 57.5	.80	24.3	45.66	-39.3 to 131.0	.25
ROM wrist								
Sagittal plane	18.1	18.20	-17.1 to 53.5	.29	60.8	42.68	13.2 to 72.2	.01*
Frontal plane	54.9	10.47	-2.6 to 23.5	.11	71.7	18.46	5.0 to 31.9	.01*
ROM thumb	9.6	1.15	-8.1 to 10.4	.79	62.6	5.34	-3.9 to 14.5	.21
ROM digits	2.6	6.91	-3.2 to 17.0	.17	41.7	10.84	-0.5 to 22.2	.06

Abbreviations: Adj, adjusted; CI, confidence interval.

*The stated treatment effect is the least-squares mean of the active treatment group minus the least-squares mean of the sham treatment group.

[†]The stated P values are not corrected for the number of outcome measures analyzed.

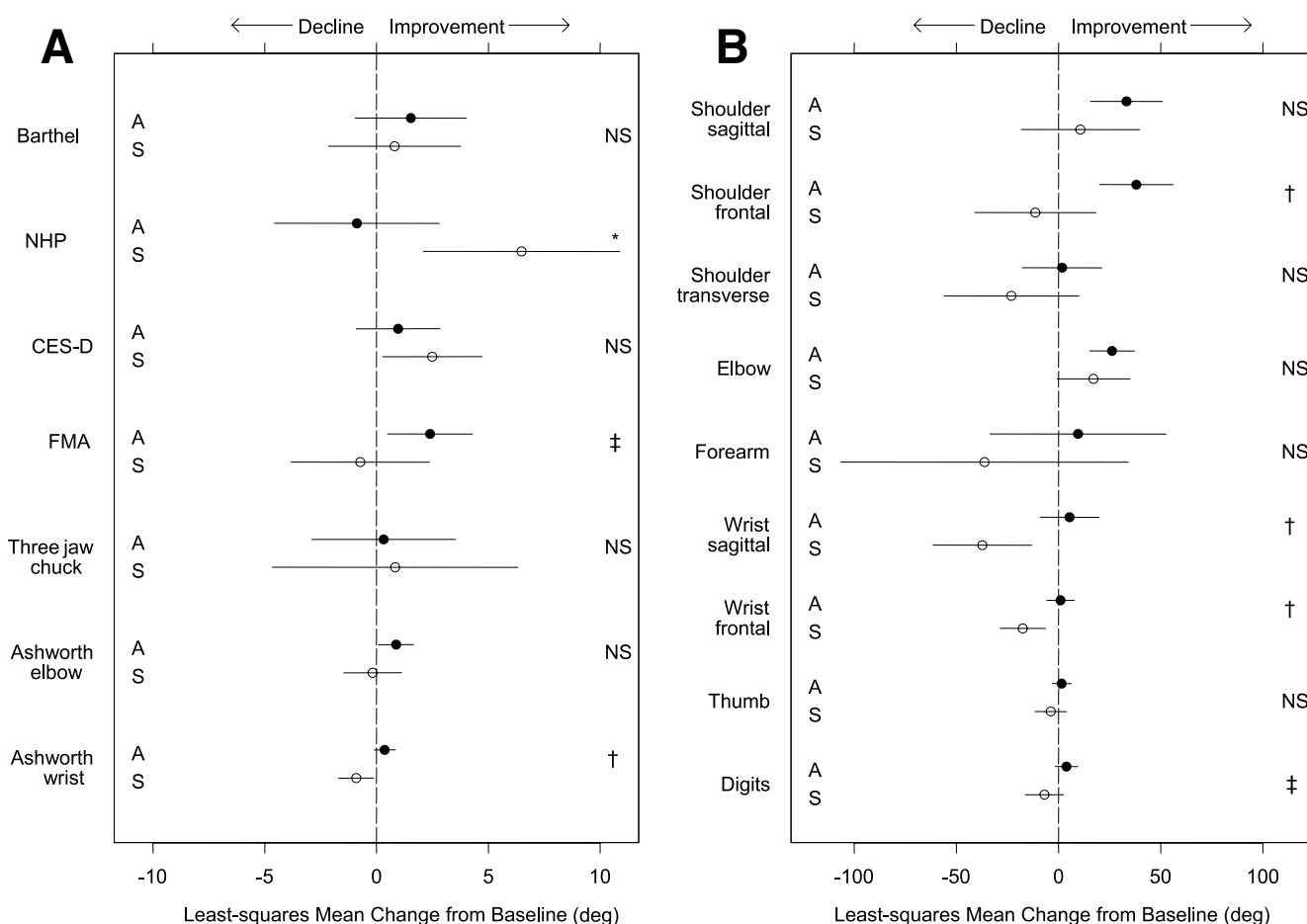


Fig 2. Least-square means estimates and 95% confidence intervals of change from baseline for per-protocol subjects. (A) ADL, mood function, strength, and UE spasticity. (B) ROM. Abbreviation: A, active treatment; NS, not significant; S, sham treatment. Note that the scales for CES-D and Ashworth scores have been inverted so that all measures show improvements to the right and declines to the left. Significant differences between active and sham acupuncture groups are indicated by *($P < .05$), †($P < .01$), and ‡($P < 0.1$).

and sham treatments.⁴¹ Lack of changes in leg spasticity in this study may have been due, in part, to the use of fewer acupuncture treatments than in our study (8 vs 20 treatments).

Also worth noting in our study is that per-protocol subjects did not show improvement in grip strength (ie, three jaw chuck measured with a dynamometer) or QOL (NHP). Results of previous studies have suggested acupuncture can positively affect these outcomes in stroke patients.^{8,13}

An important finding from our study was that our sham acupuncture protocol, which used a blunt-tipped sham needle that did not penetrate the skin, was effective as a concealable

control. This observation supports other recent studies that have endorsed the validity and credibility of this device for acupuncture RCTs.^{30,31,41} Controls in other studies of acupuncture for stroke rehabilitation have been criticized for various reasons. Standard care controls^{14,15,64} have been criticized because they do not account for the potential role of attention and other nonspecific effects of the often ritualistic administration of acupuncture.¹⁹ Studies in which acupuncture needles have been inserted shallowly have been criticized because there is no consensus on how shallow, or minimal, needling needs to be in order to be inert.^{21,22} This is especially problematic when shallow needling is done at known acupuncture points.¹⁹ Fi-

Table 4: Effects of Acupuncture on ADL, QOL, and Mood at 12-Week Follow-Up

Measure	ITT				Per-Protocol			
	Adj R^2 (%)	Treatment Effect*	95% CI	$P^†$	Adj R^2 (%)	Treatment Effect*	95% CI	$P^†$
Barthel Index (ADL)	36.9	0.11	-3.4 to 3.6	.95	43.2	0.72	-3.2 to 4.6	.70
NHP (QOL)	33.7	-1.27	-7.5 to 4.9	.68	26.0	-7.36	-13.2 to -1.6	.02
CES-D (depression)	49.5	-0.27	-3.5 to 3.0	.87	77.3	1.53	-1.4 to 4.5	.28

*The stated treatment effect is the least-squares mean of the active treatment group minus the least-squares mean of the sham treatment group.

†The stated P values are not corrected for the number of outcome measures analyzed.

nally, some recent acupuncture stroke studies have relied on low level subliminal transcutaneous nerve stimulation as a control.¹⁷ It is not clear how inert this treatment is, or whether it adequately controls for the rituals and expectations associated with true needle insertions.⁶⁵ The sham device we used represents a significant improvement over controls used in other stroke-acupuncture studies, and shows promise as a valid, effective control for future trials that evaluate acupuncture for poststroke therapy.

CONCLUSIONS

The result of ITT analyses suggest that acupuncture does not improve UE function or QOL in patients with chronic stroke symptoms. However, positive improvements in UE function found in per-protocol subjects suggest traditional Chinese acupuncture may help patients with chronic stroke symptoms. These results must be interpreted cautiously because of small sample sizes and multiple, unadjusted, post hoc comparisons. A larger, more definitive RCT using a similar design is feasible and warranted.

APPENDIX 1: POTENTIAL POOL OF ACUPUNCTURE POINTS THAT COULD BE USED IN INDIVIDUALIZED TREATMENTS, AS STIPULATED IN THE TREATMENT MANUAL³⁵

Pool A: Points for treating upper- and lower-extremity hemiparesis:

LI 15, LI 14, LI 11, LI 10, LI 4, TH 14, TH5, TH 3, Baxie, SI 9, SI 4, SI 3, GB 30, GB 31, GB 34, GB 39, GB 40, ST 34, St 36, ST 41, ST 42, LV 3, Bafeng.

Pool B: Points for treating underlying TCM etiology:

KD 3, LU 5, Ren 4, LV 3, UB 18, UB 23.

Pool C: Points for treating associated symptoms including aphasia, facial paralysis, depression, and insomnia:

Ren 23, Extra Yin Yu Yue, HT 5, HT 7, ST 5, ST 6, ST 7, LI 4, Tai Yang, TH 17, TH 5, Anmian, LV 3, UB 43, UB 45, Du 20, P 7

NOTE. Anatomic correspondences of points follow Deadman et al.⁶⁶ At each treatment, 10 to 15 points were chosen from pool A, 3 to 5 points from pool B, and 1 to 2 points from pool C.

References

- Kaptchuk TJ. The web that has no weaver: understanding Chinese medicine. Chicago: McGraw-Hill/Contemporary; 2000.
- Xu X. Acupuncture in an outpatient clinic in China: a comparison with the use of acupuncture in North America. *South Med J* 2001;94:813-6.
- Napadow V, Kaptchuk T. Patient characteristics for outpatient acupuncture in Beijing, China. *J Altern Complement Med* 2004; 10:565-72.
- Hopwood V. Acupuncture in stroke recovery: a literature review. *Complement Ther Med* 1996;4:258-63.
- Naeser MA. Acupuncture in the treatment of paralysis due to central nervous system damage. *J Altern Complement Med* 1996; 2:211-48.
- Park J, Hopwood V, White AR, Ernst E. Effectiveness of acupuncture for stroke: a systematic review. *J Neurol* 2001;248:558-63.
- Acupuncture. NIH Consensus Statement 1997;15(5):1-34.
- Sze FK, Wong E, Kevin KH, Lau J, Woo J. Does acupuncture improve motor recovery after stroke? A meta-analysis of randomized clinical trials. *Stroke* 2002;2604-19.
- Du X. Clinical observation on acupuncture treatment of 200 cases of hemiplegia. *Int J Clin Acupunct* 1990;1:230-3.
- Jiao X, Chang X, Yin K, et al. Clinical and experimental studies on acupuncture therapy of stroke-related blood stasis. *Int J Clin Acupunct* 1992;3:229-41.
- Liang R. Clinical observation and experimental studies on the treatment of sequelae of stroke by needling temporal points. *Int J Clin Acupunct* 1993;4:19-26.
- Naeser MA, Alexander MP, Stiassny-Eder D, Lannin LN, Bachman D. Acupuncture in the treatment of hand paresis in chronic and acute stroke patients—improvement observed in all cases. *Clin Rehabil* 1994;8:127-41.
- Naeser MA, Alexander MP, Stiassny-Eder D, Galler V, Hobbs J, Bachman D. Acupuncture in the treatment of paralysis in chronic and acute stroke patients—improvement correlated with specific CT scan lesion sites. *Acupunct Electrother Res* 1994;19:227-49.
- Hu HH, Chung C, Liu TJ, et al. A randomized controlled trial on the treatment for acute partial ischemic stroke with acupuncture. *Neuroepidemiology* 1993;12:106-13.
- Johansson K, Lindgren I, Widner H, Wiklund I, Johansson BB. Can sensory stimulation improve the functional outcome in stroke patients? *Neurology* 1993;43:2189-92.
- Sallstrom S, Kjendahl A, Osten PE, Stanghelle JH, Borchgrevink CF. Acupuncture in the treatment of stroke patients in the sub-acute stage: a randomized, controlled study. *Complement Ther Med* 1996;4:193-7.
- Johansson BB, Haker E, von Arbin M, et al. Acupuncture and transcutaneous nerve stimulation in stroke rehabilitation: a randomized, controlled trial. *Stroke* 2001;32:707-13.
- Kaptchuk TJ. The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance? *Ann Intern Med* 2002;136:817-25.
- Gosman-Hedstrom G, Claesson L, Klingenstierna U, et al. Effects of acupuncture treatment on daily life activities and quality of life: a controlled, prospective, and randomized study of acute stroke patients. *Stroke* 1998;29:2100-8.
- Vincent C, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med* 1995;88:199-202.
- Birch S, Hammerschlag K, Trinh K, Zaslowski C. The non-specific effects of acupuncture treatment: when and how to control for them. *Clin Acupunct Oriental Med* 2002;3:20-5.
- Sherman KJ, Cherkin DC. Developing methods for acupuncture research: rationale for and design of a pilot study evaluating the efficacy of acupuncture for chronic low back pain. *Altern Ther Health Med* 2003;9:54-60.
- Wong AM, Su TY, Tang FT, Cheng PT, Liaw MY. Clinical trial of electrical acupuncture on hemiplegic stroke patients. *Am J Phys Med Rehabil* 1999;78:117-22.
- Freuhauf H. Stroke and post-stroke syndrome. *J Chin Med* 1994; 44:23-36.
- Maclean W. Windstroke (Zhang feng). *Pacific J Orient Med* 1998;12:46-58.
- Wiseman N, Feng Y. A practical dictionary of Chinese medicine. Boston: Paradigm Publications; 1998.
- Hammerschlag R. Methodological and ethical issues in clinical trials of acupuncture. *J Altern Complement Med* 1998;4:159-71.
- Schnyer RN, Allen JJ. Bridging the gap in complementary and alternative medicine research: manualization as a means of promoting standardization and flexibility of treatment in clinical trials of acupuncture. *J Altern Complement Med* 2002;8:623-34.
- Streitberger K, Kleinhenz J. Introducing a placebo needle into acupuncture research. *Lancet* 1998;352:364-5.
- Kleinhenz J, Streitberger K, Windeler J, Bacher A, Mavridis G, Martin E. Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendonitis. *Pain* 1999;83:235-41.
- White P, Lewith G, Hopwood V, Prescott P. The placebo needle, is it a valid and convincing placebo for use in acupuncture trials?

- A randomized, single-blind, cross-over pilot trial. *Pain* 2003;106:401-9.
32. Stux B, Pomeranz G. Scientific bases of acupuncture. Berlin: Springer-Verlag; 1989.
 33. Pantheon Research. Electro-acupuncture stimulators instruction manual. Venice: Pantheon Research; 2001.
 34. Kalish LA, Buczynski B, Connell P, et al. Stop hypertension with the acupuncture research program (SHARP): clinical trial design and screening results. *Control Clin Trials* 2004;25:76-103.
 35. Allen J, Schnyer R, Hitt S. The efficacy of acupuncture in the treatment of depression in women. *Psychol Sci* 1998;9:397-401.
 36. O'Connor J, Bensky D, translators. Acupuncture: a comprehensive text. Shanghai College of Traditional Chinese Medicine. Vista: Eastland Pr; 1984.
 37. Maciocia G. The foundations of Chinese medicine. New York: Churchill Livingstone; 1989.
 38. Jianwei Z, Fan Z. A research on scalp acupuncture for cerebral infarction. *J Tradit Chin Med* 1997;17:194-7.
 39. Langevin HM, Churchill DL, Cipolla M. Mechanism signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB J* 2001;15:2275-82.
 40. Fink M, Gutenbrunner C, Rollnik J, Karst M, Vincent C, Lewith G. Credibility of a newly designed placebo needle for clinical trials in acupuncture research. Placebo controls for acupuncture studies. *Forsch Komplementarmed Klass Naturheilkd* 2001;8:368-72.
 41. Fink M, Rollnik JD, Bijak M, et al. Needle acupuncture in chronic poststroke leg spasticity. *Arch Phys Med Rehabil* 2004;85:667-72.
 42. Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Stegling S. The post-stroke hemiplegic patient. I. A method for evaluation of physical performance. *Scand J Rehabil Med* 1975;7:13-31.
 43. Fugl-Meyer AR. Post-stroke hemiplegia assessment of physical properties. *Scand J Rehabil Med Suppl* 1980;7:85-93.
 44. Duncan PW, Propst M, Nelson SG. Reliability of the Fugl-Meyer assessment of sensorimotor recovery following cerebrovascular accident. *Phys Ther* 1983;63:1606-10.
 45. Sanford J, Moreland J, Swanson LR, Stratford PW, Gowland C. Reliability of the Fugl-Meyer assessment for testing motor performance in patients following stroke. *Phys Ther* 1993;73:447-54.
 46. Bohannon RW, Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. *Phys Ther* 1987;67:206-7.
 47. Mahoney FI, Barthel DW. Functional evaluation: the Barthel index. *Md State Med J* 1965;14:61-5.
 48. Radloff LS. The CES-D scale: a self report depression scale for research in the general population. *Appl Psychol Meas* 1977;1:385-401.
 49. Hunt SM, McEwen J, McKenna S. Measuring health status: a new tool for clinicians and epidemiologists. *J R Coll Gen Pract* 1985;35:185-8.
 50. O'Brien BJ, Buxton MJ, Ferguson BA. Measuring the effectiveness of heart transplant programmes: quality of life data and their relationship to survival analysis. *J Chronic Dis* 1987;40:S137-53.
 51. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther Exp Psychiatry* 1972;3:257-60.
 52. Vincent CA. Credibility assessment in trials of acupuncture. *Complement Med Res* 1990;4:8-11.
 53. Gresham GE, Phillips TF, Wolf PA, McNamara PM, Kannel WB, Dawber TR. Epidemiologic profile of long-term stroke disability: the Framingham study. *Arch Phys Med Rehabil* 1979;60:487-91.
 54. Wolf SL, Lecraw DE, Barton LA, Jann BB. Focused use of hemiplegic upper extremities to reverse the effect of learned nonuse among chronic stroke and head-injured patients. *Exp Neurol* 1989;104:125-32.
 55. Taub E, Crago JE, Uswatte G. Constraint-induced movement therapy: a new approach to treatment in physical rehabilitation. *Rehabil Psychol* 1998;43:152-70.
 56. Carey JR, Kimberley TJ, Lewis SM, et al. Analysis of fMRI and finger tracking training in subjects with chronic stroke. *Brain* 2002;125:773-88.
 57. Carey JR, Anderson KM, Kimberley TJ, Lewis SM, Auerbach EJ, Ugurbil K. fMRI analysis of ankle movement tracking training in subjects with stroke. *Exp Brain Res* 2004;154:281-90.
 58. Volpe BT, Krebs HI, Hogan N. Robot-aided sensorimotor training in stroke rehabilitation. *Adv Neurol* 2003;92:429-33.
 59. Ferraro M, Palazzolo JJ, Krol J, Krebs HI, Hogan N, Volpe BT. Robot-aided sensorimotor arm training improves outcome in patients with chronic stroke. *Neurology* 2003;61:1604-7.
 60. Stein J, Krebs H, Frontera W, Fasoli S, Hughes R, Hogan N. Robot-aided upper limb exercise training after stroke. *Am J Phys Med Rehabil* 2004;83:720-8.
 61. de Kroon JR, van der Lee JH, IJzerman MJ, Lankhorst GJ. Therapeutic electrical stimulation to improve motor control and functional abilities of the upper extremity after stroke: a systematic review. *Clin Rehabil* 2002;4:350-60.
 62. Sommerfeld DK, Eek E, Svensson AK, Holmqvist LW, von Arbin MH. Spasticity after stroke. Its occurrence and association with motor impairments and activity limitations. *Stroke* 2004;35:134-40.
 63. Brashear A, Gordon MF, Elovic E, et al; Botox Post-Stroke Spasticity Study Group. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke [see comments]. *N Engl J Med* 2002;347:395-400.
 64. Sze FK, Wong E, Yi X, Woo J. Does acupuncture have additional value to standard poststroke motor rehabilitation? *Stroke* 2002;33:186-94.
 65. Petrie J, Hazelman B. Credibility of placebo transcutaneous nerve stimulation and acupuncture. *Clin Exp Rheumatol* 1985;3:151-3.
 66. Deadman P, Baker K, Al-Khafaji M. A manual of acupuncture. Vista: Eastland Pr; 1998.

Suppliers

- a. Model 4C; Pantheon Research, 626-A Venice Blvd, Venice, CA 90291.
- b. Sammons Preston Rolyan, 270 Remington Blvd, Ste C, Bolingbrook, IL 60440-3593.