Effects of Acupuncture Treatment on Poststroke Motor Recovery and Physical Function: A Pilot Study

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*This pilot study obtained preliminary data on the effects of acupuncture treatment combined with a standard inpatient stroke rehabilitation program on poststroke motor recovery and physical function. Thirty-two patients with acute stroke were recruited and randomized to 1 of 2 treatment arms: standard rehabilitation (control group) or a combination of acupuncture and standard rehabilitation (acupuncture group). Baseline and discharge assessments were obtained on motor recovery as measured by the Fugl-Meyer (FM) Assessment and on physical function as measured by the Functional Independence Measure (FIM). Comparisons were made between the acupuncture and control group in total FM and FIM as well as for each subscale of the FM and FIM. No differences between treatment groups were found in the total FM or the total FIM. However, statistically significant benefit due to acupuncture was observed for the FM lower extremity motor function subscale (*P *= 0.01) and the tub/shower transfer mobility subscale of the FIM (*P *= 0.03). Marginally significant benefit due to acupuncture was noted for the toilet transfer mobility subscale of the FIM (*P *= 0.09). The effectiveness of acupuncture as an adjunct to standard poststroke rehabilitation programs may be demonstrated when more specific measures of stroke motor recovery and physical function are used.*

Key Words: *Rehabilitation—Outcomes—Stroke interventions.*

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Acupuncture is one of the commonly used therapeutic modalities of Traditional Chinese Medicine.[1,2] In the United States, there is ongoing interest in the potential to improve rehabilitation effectiveness by combining Western and Eastern rehabilitation medicine techniques.[3] Several studies in the English literature have evaluated the efficacy of acupuncture as an adjunct to Western rehabilitation approaches in the treatment of stroke.[4-9] One question of interest has been whether acupuncture improves poststroke motor recovery and physical function outcomes when it is combined with a conventional Western stroke rehabilitation approach. Several studies have demonstrated no additional value of a conventional stroke rehabilitation approach combined with acupuncture treatment,[4-6] whereas other studies have reported significant differences in motor recovery and physical function as a result of acupuncture as an adjunct rehabilitation therapy.[7-9] A recent meta-analysis of acupuncture combined with a conventional stroke rehabilitation approach suggests that acupuncture provides little additional benefit to motor recovery from that of a conventional stroke rehabilitation approach alone.[10]

A primary motivation for this pilot study, a component of the Acupuncture in Stroke Assessment Project (ASAP), was to conduct a small randomized clinical trial designed to provide additional data to address some of the inconsistencies that are apparent in the literature. Studies that have specifically examined the efficacy of acupuncture combined with conventional stroke rehabilitation approaches in the treatment of acute, first-time onset of stroke have 3 major inconsistencies: 1) reported skill

levels of the clinicians performing acupuncture treatment range from very experienced acupuncturists trained by Traditional Chinese Medicine practition-ers,[4,8] to physical therapists trained to do acupuncture,[6] to unknown skill levels[7,9]; 2) acupuncture treatment sessions were consistently reported to be of 30-min duration, yet treatment frequency ranged from 2 times/week for 10 weeks[5,6,9] to 3–4 times for 4–8 weeks,[4,8] to every day for 2 weeks[7]; and 3) the choice of outcomes appeared to be associated with acupuncture benefit in that more specific (rather than global) indices of motor or physical function demonstrated favorable results due to acupuncture,[7] whereas the use of more global measures demonstrated no effect of acupuncture.[4-6]

This pilot study was designed to provide preliminary data to investigate the efficacy of acupuncture treatment as an adjunct to a conventional inpatient acute rehabilitation program in improving motor recovery and physical function after acute, first-time stroke. In this study, specific outcome measures associated with motor and physical function were used because recent basic studies suggest that the mechanisms of acupuncture effectiveness may be associated with enhanced sensorimotor function in cortical areas that are typically damaged and result in motor deficits after stroke.[10-20] We demonstrate that measurement specificity can be a factor in the determination of acupuncture effectiveness in poststroke rehabilitation.

METHODS

Study Population

Patients admitted to the inpatient stroke rehabilitation unit at Daniel Freeman Rehabilitation Center, Los Angeles, California, were screened for eligibility to participate in this study. Inclusion criteria included acute stroke resulting in hemiparesis, diagnosed by a neurologist and confirmed with CT or MRI scan. Exclusion criteria included a) history of a previous stroke, b) inability to cooperate or follow directions for examination and tests, c) coma or subarachnoid hemorrhage, d) any other acute life-threatening illness or severe complications, e) significant systemic disease or disease that interferes with the assessment of stroke, and f) patients who were not independent in activities of daily living prior to stroke onset. Study enrollment occurred within 60 days of stroke onset.

Study Design

The study was a single-blinded, randomized clinical trial carried out in a stroke inpatient rehabilitation unit. After inclusion and institutional review board–approved consent, participants were randomized within strata defined by stroke type (ischemic or hemorrhagic) to either the control or acupuncture group. The control group received conventional stroke rehabilitation care (3 h of physical, occupational, and/or speech therapy, 6 days per week) for the duration of the inpatient stay. The acupuncture group received conventional stroke rehabilitation care and 30 additional minutes of acupuncture therapy 7 days per week for 2 weeks (14 total acupuncture sessions) during the inpatient stay.

The acupuncture protocol was designed by a PhD-trained acupuncturist from Beijing University, Department of Traditional Chinese Medicine and Pharmacology, with more than 10 years of teaching and practice experience in the United States. The acupuncture protocol was administered by 8 acupuncturists trained at the Emperor's College of Oriental Medicine with California acupuncture licensure and a minimum of 1 year clinical experience.

To ensure consistency across the acupuncturists, an individualized treatment approach was not used. Instead, a standardized approach that included manual needle insertion (not electroacupuncture) to the hemiparetic limb, in which the acupuncturist could select specific sites based on patient symptoms, was used. The acupuncture points included were Du 20 (Bai Hui), Du 19 (Qian Ding), Du 21 (Hou Ding), UB 7 (Tong Tian), GB 20 (Feng Chi), Du14 (Da Zhui), Ren 6 (Qi Hai), Ren12 (Zhong Wan), and St 25 (Tian Shu). We also selected the supplementary points, which included LI 15 (Jian Yu), LI 11 (Qu Chi), SJ 5 (Wai Guan), LI 4 (He Gu), and Lu 7 (Lie Que) for upper limbs; and GB 31 (Feng Shi), St 36 (Zuo San Li), GB 34 (Yang Ling Quan), Sp 6 (San Yin Jiao), St 40 (Feng Long), St 41(Jie Xi), and Liv 3 (Tai Chong) for lower limbs. Within 2 weeks of the stroke episode, we added Ba Feng as well as Ren 23 (Lian Quan), Ht 5 (Tong Li) for aphasia, St 4 (Di Cang), SI 18

(Quan Liao), St 6 (Jia Che) for facial paralysis, and UB 6 (Cheng Guang), Gb 37 (Guang Ming) for vision problems.

Measurement

An occupational therapist and physical therapist blinded to group assignment performed assessments at baseline (within 3 days of admission) and discharge. The therapists were trained and certified in the study assessment procedures. The primary outcome measures for this study were changes in the individual items of the Fugl-Meyer (FM) assessment of physical performance and selected physical functional items of the Functional Independence Measure (FIM). These outcome measures were specifically selected to reflect motor and physical function that is most parallel to possible mechanisms associated with acupuncture effectiveness. The FM is a valid and reliable measure of stroke severity that is graded on a 3-point ordinal scale for a total score of 226 points.[21] However, recent review of the FM as an assessment tool has revealed that specific subcomponents of the FM are, in fact, not reliable, suggesting that a subscale analysis of the FM may provide a more specific evaluation of treatment effect rather than using the total FM score.[22] Therefore, the FM was analyzed separately for the upper extremity (UE) and lower extremity (LE) in each of the 5 main subscales (joint motion, joint pain, motor function, sensation, balance), resulting in 10 items for analysis (Total FM, 226 points; UE joint motion, 24 points; LE joint motion, 20 points; UE joint pain, 24 points; LE joint pain, 20 points; UE motor function, 66 points; LE motor function, 34 points; UE sensation, 12 points; LE sensation, 12 points; balance, 12 points).

The FIM is a measure of functional limitation and reflects that amount of assistance needed to complete activities of daily living.[23] Each item is graded on a 7-point ordinal scale from a score of 1 (total assistance) to a score of 7 (complete independence). Selected physical function items of the FIM were used for analysis and included the following items: dressing upper body, dressing lower body, bed/chair/wheelchair transfers, toilet transfers, tub/shower transfers, walk/wheelchair locomotion, stair locomotion.

Quality Control

After the completion of the study, an independent physical therapist with research expertise in neurorehabilitation (KJS) reviewed all patient charts for consistency and accuracy. Questionable items were clarified and validated.

Statistical Analysis

For this pilot study, recruitment was limited by administrative factors, including the availability of study personnel certified to conduct the study. Therefore, it was projected that 32 eligible participants could be recruited, treated, and followed during the planned study period of 1 year. Power calculations indicated that a sample size of 32 (16/treatment arm) was sufficient to detect a treatment effect size of 0.9 or greater with 80% power.

Baseline demographic and clinical characteristics were compared between treatment groups using chi-square or Fisher's exact tests for categorical variables and Wilcoxon rank sum tests for continuous variables. Baseline and discharge functional measures (FM and FIM) and changes (discharge – baseline) in functional measures were contrasted between treatment groups using the Wilcoxon rank sum test and within groups using the Wilcoxon signed rank test. All the analysis was conducted using SAS (Cary, NC) at the 0.05 significance level (2-sided).

RESULTS

Figure 1 summarizes the trial profile. A total of 32 eligible patients (15 females and 17 males) agreed to participate in the study. After informed consent was obtained, 16 patients were randomized to the acupuncture group and 16 to the control group. The mean ± *SD* time from stroke onset to admission to the stroke rehabilitation unit was 17.3 ± 16.4 days. No adverse events due to acupuncture treatment were reported.

Table 1 summarizes the demographic, baseline clinical, and discharge characteristics for each of the treatment groups. On average, patients randomized to the acupuncture group were significantly older than those randomized to the control

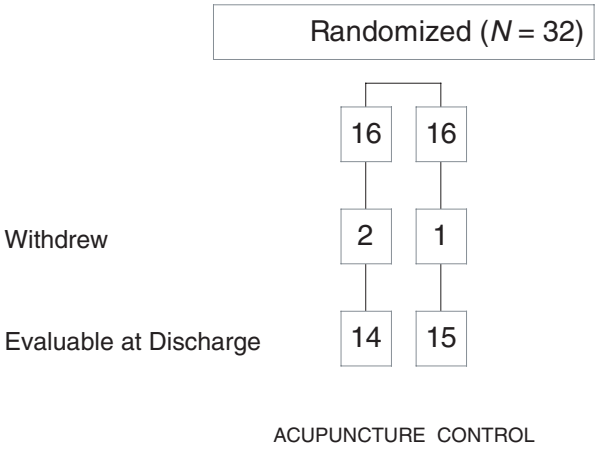

Figure 1. Trial profile for the Acupuncture Treatment on Poststroke Motor Recovery and Physical Function (Acupuncture in Stroke Assessment Project).

group (P = 0.01). No significant differences were found between treatment groups for gender, ethnicity, side of stroke, stroke type, lesion site, time from stroke onset to admission to the rehabilitation unit, and prior experience with acupuncture treatment (all $P > 0.05$).

The average length of rehabilitation was 22.1 ± 5.0 days. During rehabilitation, 1 patient (acupuncture group) died and 2 patients (1 from each treatment group) were discharged early from the rehabilitation unit and did not complete the treatment and/or discharge assessments. Therefore, outcomes at discharge were available for 29 patients (14 acupuncture, 15 control). As shown in Table 1, no significant differences between treatment groups were found for number of days in rehabilitation or discharge disposition ($P >$ 0.05).

Table 2 summarizes the FM baseline, discharge and change (discharge – baseline) total, and subscale scores for the 29 patients with discharge evaluations. At baseline, the lower extremity (LE) sensation score was significantly lower for the acupuncture group compared to the control group (P < 0.01). No differences between treatment groups at baseline were found for the total FM score or any other subscale.

Both groups demonstrated on average a 4% to 5% improvement at discharge in the total FM score (P < 0.05). However, there was no difference in the average change in total FM scores between the control and acupuncture groups (P = 0.91). Examination of the change in FM subscales at discharge revealed that compared to the control group the improvement in LE motor function was significantly greater in the acupuncture group (P = 0.01). No other treatment differences in FM subscales (upper extremity, UE motor function, UE or LE joint motion, joint pain, sensation, or balance) were found (all $P > 0.05$).

Table 3 summarizes the FIM baseline, discharge and change FIM physical function total, and subscale scores for the 29 patients with discharge evaluations. At baseline, no differences between treatment group at baseline were found for the total FIM score or any other subscale. At discharge, both treatment groups demonstrated a significant improvement in the total FIM score and each physical function subscale FIM ($P < 0.05$). As with the motor recovery analysis, there were no statistically significant differences between the control and acupuncture groups when comparing the change scores for the total FIM (P = 0.13). However, patients who received acupuncture as an adjunct to standard rehabilitation demonstrated significantly greater improvement in tub/shower transfer mobility (P = 0.03) and a trend for greater improvement in toilet transfer mobility (P = 0.09).

DISCUSSION

This study investigated the efficacy of acupuncture as an adjunct to conventional stroke rehabilitation during the acute, inpatient rehabilitation phase poststroke. Acupuncture procedures were standardized and treatment sessions delivered daily for 14 days of an average 22-day inpatient stay by highly trained acupuncturists who were licensed to practice acupuncture in California. Blinded evaluators were used for all baseline and discharge measures.

As in other studies that have investigated the additional value of acupuncture when combined with conventional stroke rehabilitation,[4-6] we found that both groups made improvements in motor recovery and physical function, with no differences between groups when global measures of motor and physical function were used. However, when subscores of these global measures were used, differences between groups were apparent. Patients who received acupuncture as an adjunct to conventional stroke rehabilitation demonstrated increased gains in motor recovery of lower limb movements compared to those patients who

Table 1. Demographic and Baseline Characteristics by Treatment Assignment

Characteristic		Acupuncture (n = 16)	Control (n = 16)	P value
Age		66.5 ± 8.8	55.7 ± 12	0.01‡
Gender	Female	7 (43.8%)	8 (50.0%)	0.72*
	Male	9 (56.3%)	8 (50.0%)	
Ethnicity	African American	7 (43.8%)	6 (37.5%)	0.88*
	Asian	1 (6.2%)	2 (12.5%)	
	Hispanic	4 (25.0%)	3 (18.8%)	
	Caucasian	4 (25.0%)	5 (31.2%)	
Side of stroke	Bilateral	1 (6.3%)	0 (0.0%)	0.24*
	Left	8 (50.0%)	4 (25.0%)	
	Right	7 (43.8%)	11 (68.8%)	
	Missing	0 (0.0%)	1 (6.2%)	
Stroke type	Hemorrhage	2 (12.5%)	2 (12.5%)	0.78*
	Infarct	7 (43.8%)	7 (43.8%)	
	Lacunar infarct	7 (43.8%)	6 (37.5%)	
	Missing	0 (0.0%)	1 (6.3%)	
Lesion site	Brainstem	2 (12.5%)	2 (12.5%)	0.87*
	Cortical	6 (37.5%)	7 (43.75%)	
	Striatocapsular	3 (18.8%)	4 (25.0%)	
	Not recorded	5 (31.3%)	3 (18.8%)	
Onset to rehab admission (days)		16.8 ± 16.5	17.9 ± 17.0	0.75‡
Previous acupuncture	No	15 (93.8%)	12 (75.0%)	0.33†
	Yes	1 (6.3%)	4 (25.0%)	
Rehab admission to discharge (days)		21.7 ± 5.1	22.5 ± 5.0	0.66‡
Disposition	Died	1 (6.3%)	0 (0.0%)	0.50*
	Home	13 (81.2%)	14 (87.5%)	
	Nursing home	2 (12.5%)	1 (6.3%)	
	Missing	0 (0.0%)	1 (6.3%)	

*P values from χ^2 test.
†P values from Fisher's exact test.
‡P values from Wilcoxon Mann-Whitney test.

did not receive acupuncture. Greater change in lower extremity motor control could contribute to the increased gains in functional transfer ability evident in the functional performance of the acupuncture compared to control group.

One explanation for the lack of a treatment effect reported in previous acupuncture studies may be the selection of tests and measures that are not compatible with the proposed physiologic mechanisms of acupuncture. Recent work has specifically investigated the physiological mechanisms that may underlie the therapeutic effect of acupuncture. Acupuncture may provide a form of sensory stimulation that stimulates polymodal-type receptors providing a source of peripheral afferent stimulation via the spinal cord to central nervous system structures.[11-13] After stroke, acupuncture has been found to induce changes in regional cerebral blood flow (rCBF) that may increase flow to hypoperfused areas of the ischemic penumbra.[14] Changes in rCBF have also been attributed to acupuncture in the hypothalamus-limbic systems in response to stimulation of analgesic points, providing further support for localized cortical effects attributable to acupuncture stimulation.[15,16] Additionally, stroke recovery has also been associated with neurotrophic factors that are capable of supporting neuronal survival after stroke.[17] Recent animal work is beginning to demonstrate that acupuncture can enhance neurotrophic factor expression that promotes cell survival and prevents apoptosis.[18-20]

If the mechanism of acupuncture effectiveness after stroke is related to factors that influence afferent inputs and intrinsic cortical circuits associated with sensorimotor function, then measures of acupuncture effectiveness should be used that are more closely related to neurorecovery. For that reason, our results suggest that the motor subscore of the FM may be a more sensitive measure of

Table 2. Mean (*SD*) Baseline, Discharge and Change (Discharge – Baseline) in Fugl-Meyer Total and Subscale Scores by Treatment Assignment

	Acupuncture (n = 14)			Control (n = 15)			
Scale	Baseline	Discharge	Change	Baseline	Discharge	Change	P
Total Fugl-Meyer (226 max)	138.4 ± 31.8	143.9 ± 38.9	5.5 ± 13.8†	157.3 ± 35.6	165.0 ± 36.3	7.7 ± 12.3†	0.91
Joint Motion: LE (20 max)	19.1 ± 1.1	18.9 ± 1.2	–0.3 ± 1.3	19.0 ± 1.4	19.1 ± 1.2	0.1 ± 1.2	0.42
Joint Motion: UE (24 max)	22.3 ± 2.1	21.1 ± 2.7	–1.1 ± 1.1†	22.8 ± 1.7	22.5 ± 1.7	–0.3 ± 1.5	0.11
Joint Pain: LE (20 max)	18.9 ± 1.9	18.9 ± 2.9	–0.1 ± 2.5	19.0 ± 1.9	18.6 ± 2.8	–0.4 ± 1.8	0.41
Joint Pain: UE (24 max)	21.0 ± 4.1	19.9 ± 3.9	–1.1 ± 2.1	21.5 ± 2.9	20.7 ± 4.0	–0.7 ± 3.3	0.45
Motor Function: LE (34 max)	13.9 ± 7.6	18.5 ± 8.1	4.6 ± 2.8†	17.7 ± 8.4	18.6 ± 9.7	0.9 ± 3.9	0.01
Motor Function: UE (66 max)	18.9 ± 19.6	21.0 ± 20.3	2.1 ± 5.1	27.2 ± 22.6	33.9 ± 22.1	6.7 ± 9.3†	0.13
Sensation: LE (66 max)	8.8 ± 3.8*	9.4 ± 3.6	0.6 ± 3.3	11.2 ± 1.26	11.5 ± 0.74	0.3 ± 1.2	0.32
Sensation: UE (12 max)	8.5 ± 4.2	8.4 ± 4.8	–0.1 ± 3.8	10.7 ± 1.88	10.9 ± 1.36	0.2 ± 1.5	0.52
Balance (12 max)	6.9 ± 1.5	7.9 ± 1.9	0.9 ± 1.0†	8.3 ± 2.8	9.2 ± 2.48	0.9 ± 1.4†	0.62

LE = lower extremity; UE = upper extremity; P = P value from Wilcoxon Mann-Whitney test.
*Significant difference between acupuncture and control group at baseline ($P < 0.10$).
†Significant difference between baseline and discharge ($P < 0.05$).

Table 3. Mean (*SD*) Baseline, Discharge and Change (Discharge – Baseline) for Functional Independence Measure (FIM) Total and Subscale Scores by Treatment Assignment

Scale	Acupuncture (n = 14)			Control (n = 15)			P
	Baseline	Discharge	Change	Baseline	Discharge	Change	
Total FIM (49 max)	15.9 ± 5.7	27.1 ± 7.7	11.2 ± 4.5†	19.9 ± 8.8	28.4 ± 8.5	8.5 ± 3.8†	0.13
Self Care: Dressing, upper body	3.4 ± 1.1	4.9 ± 0.9	1.4 ± 0.7†	3.6 ± 1.1	4.9 ± 0.9	1.3 ± 0.8†	0.81
Self Care: Dressing, lower body	2.4 ± 1.1	3.6 ± 1.2	1.2 ± 0.6†	2.8 ± 1.5	3.9 ± 1.2	1.1 ± 0.9†	0.98
Mobility: Bed/chair/wheelchair transfers	2.6 ± 1.2	4.1 ± 1.2	1.6 ± 0.8†	3.3 ± 1.3	4.5 ± 1.5	1.2 ± 0.7†	0.27
Mobility: Toilet transfer	2.4 ± 1.2	4.1 ± 1.3	1.7 ± 1.0†	3.2 ± 1.4	4.4 ± 1.4	1.2 ± 0.6†	0.09
Mobility: Tub/shower transfer	2.3 ± 1.1*	4.0 ± 1.3	1.7 ± 1.0†	3.2 ± 1.4	4.2 ± 1.1	1.0 ± 0.6†	0.03
Locomotion: Walk/wheelchair	1.6 ± 0.8	3.9 ± 1.5	2.2 ± 1.5†	2.1 ± 1.5	3.5 ± 1.8	1.4 ± 1.5†	0.12
Locomotion: Stairs	1.1 ± 0.4	2.5 ± 1.7	1.4 ± 1.5†	1.7 ± 1.6	3.0 ± 1.8	1.3 ± 1.4†	1.00

P = P value from Wilcoxon Mann-Whitney test.
*Significant difference between acupuncture and control group at baseline ($P < 0.10$).
†Significant difference between baseline and discharge ($P < 0.05$).

motor recovery that can detect an acupuncture treatment effect. Other authors have also suggested that a lack of acupuncture treatment effect may be due to the use of sum scores or levels of measurement that are not responsive.[5] Although most acupuncture studies have intentionally selected stroke outcome instruments that are commonly used internationally, such as the Barthel Index, Functional Independence Measure, and total Fugl-Meyer score,[10] these instruments are inadequate to detect changes in motor recovery after stroke and are not reasonably associated with the mechanisms that may account for acupuncture effectiveness.

The issue of stroke outcome measurement is highlighted in a recent review article on the measurement properties of the FM scale in which the reliability and validity of the UE and LE motor domain scores are high whereas the other domains (sensation, balance, joint range of motion, and pain) are not.[22] Therefore, we recommend that future clinical trials evaluating the effect of acupuncture on poststroke motor recovery should utilize outcome measures that are reliable, valid, and sensitive enough to detect changes in motor recovery after stroke.

Study Limitations

Participants in the acupuncture group not only received acupuncture treatment but also more attention than patients in the conventional stroke rehabilitation care control group. Although the study evaluators were blinded to the treatment assignment, the patients were not blinded. Therefore, one limitation of this pilot study is that we did not measure the effect of patient expectation. It has been reported in the literature that expectation can activate serotonergic pathways in depression, dopamine-release in patients with Parkinson's disease, and opioid pathways in pain.[24-26] Such studies make it reasonable to assume that the rather strong effects of acupuncture could at least in part be due to expectation.

A 2nd limitation of this pilot study is that no sham acupuncture was used. However, the evaluation of outcome was assessed by a therapist blinded to treatment.

A 3rd limitation of this pilot study is that follow-up data postdischarge were not available. Although the initial study plan considered long-term follow-up, limited resources did not permit patient postdischarge clinic or home visits for assessing motor function.

Although there was a baseline difference in age between the groups, reanalysis of outcomes adjusting for age (ANCOVA) did not change the conclusions. This was due to the fact that the correlational relationship of the subscales with age was < 0.3, in which case covariate adjustment is not necessary.[27] Furthermore, there was a baseline difference in age between the groups; the fact that improvement was more pronounced in the acupuncture group, which was the older group, suggests that the results could be stronger if the groups were matched on age.

We do not believe a limitation is that both total scores and subscales of the FM and the FIM are compared between treatment groups without making adjustments for multiple comparisons. This is the standard operating procedure for comparison of questionnaires that are measuring specific functions (subscales) and producing an overall total score. In addition, we have followed current guidelines by a) reporting results for hypotheses defined a priori and b) reporting both the significant and nonsignificant findings.[28]

CONCLUSIONS

This pilot study is consistent with previous studies that have examined acupuncture treatment as an adjunct to conventional stroke rehabilitation. When global measures are used, there are no differences in motor recovery or physical function associated with acupuncture. However, when more responsive measures are used, acupuncture effects are evident. Future work that investigates the efficacy and effectiveness of acupuncture treatment poststroke should incorporate levels of measurement that are sensitive to the physiologic mechanisms that may underlie acupuncture effects.

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