

# A one year follow-up study on the effects of acupuncture in the treatment of stroke patients in the subacute stage: a randomized, controlled study

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**Objective:** We recently reported that acupuncture treatment of stroke patients in the subacute stage gave additive therapeutic benefit. The purpose of the present study was to determine, approximately one year after discharge from the rehabilitation hospital, whether the group differences still remained.

**Design:** The patients were randomized into two groups: one acupuncture group and one control group, considering gender and side of hemispherical localization of lesion. With regard to the main parameters the groups were comparable at baseline.

**Setting:** Initially, 45 stroke patients admitted to Sunnaas Rehabilitation Hospital were included in the study: median 40 days post stroke.

**Subjects:** Forty-one of the patients were available one year after the treatment period: 21 patients in the acupuncture group and 20 controls.

**Intervention:** All subjects received an individually adapted, multidisciplinary rehabilitation programme. The acupuncture group received additional treatment with classical acupuncture for 30 min three to four times weekly for six weeks.

**Main outcome measures:** The patients were evaluated at inclusion, after six weeks and approximately 12 months after discharge from the rehabilitation hospital. The Motor Assessment Scale (MAS) for stroke patients, Sunnaas Index of Activity of Daily Living (ADL) and Nottingham Health Profile (NHP) were used. In addition, the social situations of the patients were recorded at one year follow-up.

**Results:** The results show that the acupuncture group improved significantly more than the controls, both during the treatment period of six weeks, and even more during the following year, both according to MAS, ADL, NHP and the social situation.

**Conclusion:** Although the mechanism of the effects is debatable, there seems to be a positive long-term effect of acupuncture given in the subacute stage post stroke.

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## Introduction

We recently<sup>1,2</sup> reported that acupuncture treatment of stroke patients in the subacute stage gave additive therapeutic benefit on motor function and activities of daily living (ADL) compared with control patients during a period of six weeks at a rehabilitation hospital. Only the acupuncture group rated a significantly improved quality of life. All these patients were given a comprehensive, multidisciplinary treatment. The same amounts of physiotherapy, occupational therapy, speech therapy and neuropsychological intervention were given in both the acupuncture group and the control group. The acupuncture group, however, was given additional acupuncture treatment three to four times a week of 30 min duration for six weeks. The control group received no additional treatment. Our results were in accordance with those of a Swedish study on acupuncture treatment of stroke patients in the acute stage, indicating positive short- and long-term effects of acupuncture.<sup>3,4</sup>

The purpose of the present study was to examine, approximately one year after discharge from the rehabilitation hospital, whether the group differences still remained. In addition, we wanted to compare the social situations of the stroke patients.

Depression is recognized as a poststroke complication and the phenomenon has been extensively studied over the past 20 years.<sup>5-7</sup> In our study acupuncture seemed to have favourable effects on depression and other variables of life quality during the six week treatment period.<sup>1,2</sup> Anderson *et al.*<sup>7</sup> conclude that 'the burden of symptoms such as lack of energy, insomnia, tiredness and lack of concentration could be troublesome or even prevent the patient benefiting fully from rehabilitation'. In traditional Chinese medicine it is said to be crucial to treat not only the cause of the disease but also the accompanying symptoms, and we wanted to find out whether our acupuncture treatment could influence those restraining factors for a successful recovery over prolonged time.

## Materials and methods

After informed consent, 45 patients with hemiparesis (35 with cerebral infarction and 10 with cerebral hemorrhage) following a first ever stroke, were consecutively randomized into two groups (24 in the acupuncture and 21 in the control group), according to gender and site of hemispheric lesion. The occurrence of accompanying diseases and risk factors happened to be equally distributed between the groups.

All patients underwent a routine neuropsychological screening battery (NPG) in order to determine prevalences of aphasia, apraxia and perceptual disturbances (neglect).<sup>8</sup> The patients were screened on admission to the hospital, and the findings from the neuropsychologists concluded: aphasia present in 12 patients in the acupuncture group versus seven in the control group, apraxia present in nine versus three and neglect present in 10 versus six patients, respectively. Thus, accidentally, there was a tendency towards a predominance of severe neuropsychological impairments in the acupuncture group, but the difference was not statistically significant.

All patients in the study received multidisciplinary rehabilitation by the staff members of the stroke team. More details about the treatment are described in our earlier report.<sup>1,2</sup>

The acupuncture group was treated by two acupuncturists trained in traditional Chinese medicine (TCM), and who were not involved in the routine management of the patients. Regular supervision was given by TCM doctors from the China Rehabilitation Research Center, Beijing. Acupuncture points were selected in compliance with TCM's principles for treating stroke in the postacute stage with the use of body points and scalp acupuncture.<sup>12,13</sup>

In our follow-up study, 41 patients were examined. There were three drop-outs in the acupuncture group and one in the control group; one died and one was hospitalized with femoral fracture from the acupuncture group, and two were excluded because they were not available due to poor health (one from each group). There were no statistical differences between the groups regarding age, gender or time from stroke onset till inclusion (Figure 1). The median follow-up period after discharge was 55 weeks (range

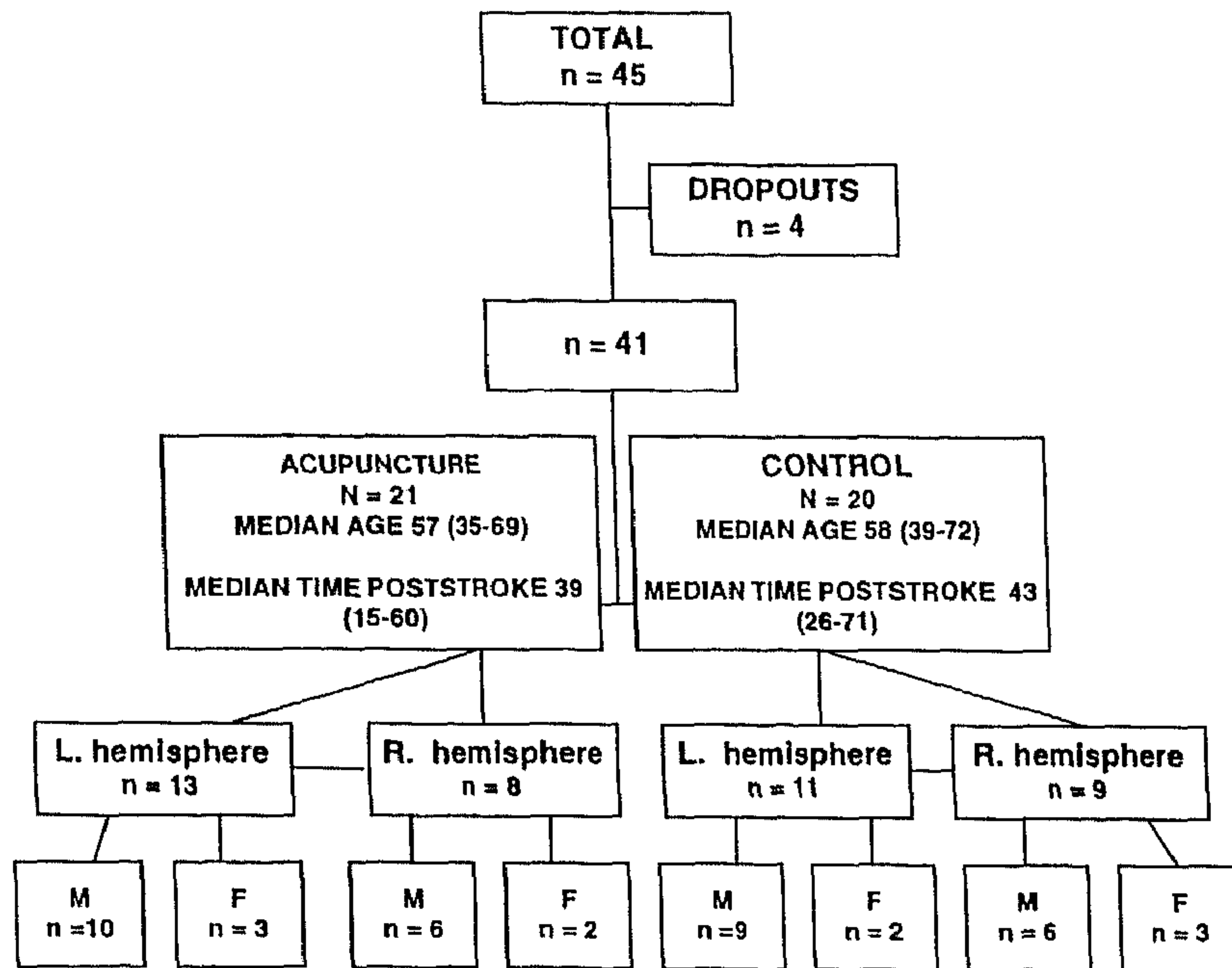


Figure 1 Subjects included and randomized in the acupuncture study

34–73) in the acupuncture group and 57 weeks (range 34–77) in the control group. The reason for this wide range was due to practical factors with organization of the follow-up study.

All patients were evaluated with identical evaluation indices three times: at baseline when included (test 1), after the treatment period of six weeks (test 2), and approximately one year after discharge from the hospital (test 3). The three indices were Motor Assessment Scale for stroke patients (MAS),<sup>9</sup> Sunnaas Index of Activity of Daily Living (ADL)<sup>10</sup> and Nottingham Health Profile (NHP).<sup>11</sup> In order to make the administration of assessments as consistent as possible from one test point to the other, the procedure was standardized for all patients.

The assessment of MAS was videorecorded by the acupuncturists in the same way for all patients at all three test times. The videotapes were evaluated by a physiotherapist with no connection either to the study or to the stroke department, and who was unaware to which group the patients belonged.

The Sunnaas Index of ADL is routinely used by the occupational therapists in the stroke unit,

and it was assessed by the patient's individual occupational therapist the first two times. Since the index is found to have sufficient reliability between therapist's and patient's self-evaluation, the patients were asked to fill in the index themselves at test 3 (K. Vardeberg, personal communication 1996).

NHP was filled in by the patients alone or together with a family member or relative. For those with cognitive impairments, the acupuncturists assisted the patients in explaining the statements.

MAS scores range between 0 and 48 (optimal function). Minimum score for independency at home has not been evaluated so far. However, we assume that a score of about 20 is a minimum. Sunnaas Index of ADL scores range from 0 to 36 (full independency). A score of 12 is in clinical use as the minimum for returning home with personal and technical assistance. NHP is a self-reporting questionnaire about life quality and is divided into two parts: NHP I measures emotional reactions, sleeping problems, loss of energy, pain, physical movement and social isolation, and NHP II measures the ability to pur-

sue activities such as work, jobs around the home, social life, home life, sex life, hobbies and holidays. All these items give scores from 0 to 100, with 0 as the best. In the follow-up study one patient in the acupuncture group was unable to answer due to global aphasia.

During the last examination, we obtained a verbal description of the social situation of each patient from the person her- or himself and/or supplemented by the spouse or another close family member who accompanied the patient to the outpatient clinic during test 3.

During the period between discharge from our hospital and the follow-up examination approximately one year later the patients were treated by the first-line health services according to advices from the rehabilitation hospital. All patients were prescribed regular physiotherapy and/or self-administrated exercise one to three times weekly. None of the patients in the acupuncture group received additional acupuncture during this period, while two of the controls started with acupuncture therapy on their own initiative. The medical treatment was controlled by the patients' general practitioners.

### Statistics

The comparison of changes over time from baseline to one year after discharge from the hospital was performed by analysis of variance (ANOVA) with repeated measurements. The groups were further compared with regard to the status one year after discharge by analysis of

covariance (ANACOVA) with the baseline measurement, age and sex as covariates. The changes from baseline to one year after submission within the groups were analysed by Wilcoxon's signed rank test. Discrete data were analysed by Fisher's exact test for comparisons of the groups. All comparisons of the two groups regarding MAS were performed on log-transformed data.

As four patients were drop-outs at one-year follow-up, their latest registration (six weeks after deadline) were used also one year later, in order to check possible influence of such drop-outs. Two of these patients were not able to answer NHP at all. Thus, their NHP scores were not included in the results.

All tests were performed two-tailed with a significance level of 5%.

### Results

Table 1 shows the results of the MAS evaluation for the three tests. The situation was significantly improved in both groups ( $p \leq 0.0001$  in the acupuncture, and  $p \leq 0.0002$  in the control group, respectively) (ANOVA). There were highly significant differences between the groups with regard to changes over time from baseline to one year after treatment ( $p = 0.002$ ) (ANACOVA), and with regard to the status one year after treatment ( $p = 0.001$ ) (Wilcoxon), when the analyses were adjusted for the baseline value. Without this adjustment there were no significant differences between the end results.

Table 2 shows the three evaluations with Sun-

**Table 1** Motor Assessment Scale (MAS) for the stroke patients in the acupuncture study

	MAS			Significance from baseline to 12 months
	Baseline	6 weeks	12 months	
Acupuncture ( <i>n</i> = 21)	19.2 (9.3) 15.0–23.0	29.1 (9.7) 24.0–33.0	35.0 (10.0) 27.0–46.0	$p \leq 0.0001$
Control ( <i>n</i> = 20)	21.2 (10.2) 13.5–29.0	26.3 (11.1) 16.5–37.0	29.6 (11.4) 18.0–41.5	$p \leq 0.0002$
Significance between groups	NS	$p = 0.002$	$p = 0.001$	

Values are means (SD) and 25–75 percentiles, respectively.

naas Index of ADL. The situation was significantly improved in both groups ( $p \leq 0.0001$ ). However, significant differences between the two groups in favour of the acupuncture group were found, both with regard to changes over time from first to third evaluation ( $p = 0.001$ ), and with regard to the status after one year ( $p = 0.0002$ ).

Table 3 shows the scores with NHP I on the three occasions. The two groups showed different time profiles. The analysis showed a significant difference between the two groups with regard to changes over time from baseline to one year after ( $p = 0.0003$ ), and also a significant difference one year after discharge ( $p \leq 0.0001$ ). The acupuncture group improved during the whole period ( $p = \leq 0.0001$ ), while the control group remained almost unchanged ( $p = 0.50$ ).

Table 4 shows that the six different subscores of NHP I gave significant differences in favour of the acupuncture group for the assessment of

emotional reactions, sleeping problems, physical movement and loss of energy. There were no differences between the groups for the assessment of social isolation and pain. There were significant improvements in the acupuncture group regarding emotional reaction, sleeping problems, physical movement and loss of energy. The control group reported a significant worsening of emotional reactions and loss of energy ( $p = 0.03$  and  $p = 0.007$ , respectively), but significant improvement in physical movement ( $p = 0.02$ ).

Table 5 shows the scores for NHP II during the three tests. There were no differences between the two groups after the treatment period of six weeks. One year later, however, the acupuncture group had significantly improved regarding changes over time ( $p = 0.0002$ ), and in status ( $p = 0.0001$ ) compared with the controls. The control group remained at the same level. There was a significant improvement in the acupuncture

**Table 2** Sunnaas Index of Daily Living (ADL) for the stroke patients in the acupuncture study

	ADL			Significance from baseline to 12 months
	Baseline	6 weeks	12 months	
Acupuncture ( $n = 21$ )	19.0 (6.4) 13.0–23.0	24.8 (6.6) 21.0–29.0	31.9 (4.9) 30.0–36.0	$p \leq 0.0001$
Control ( $n = 20$ )	20.4 (6.6) 15.5–26.5	24.3 (6.3) 19.0–30.5	26.5 (5.8) 23.0–30.5	$p \leq 0.0001$
Significance between groups	NS	NS	$p = 0.0002$	

Values are means (SD) and 25 and 75 percentiles, respectively.

**Table 3** Nottingham Health Profile (NHP) estimated by the subjective rating scores for the stroke patients in the acupuncture study

	NHP I			Significance from baseline to 12 months
	Baseline	6 weeks	12 months	
Acupuncture ( $n = 20$ )	27.0 (17.1) 13.6–35.8	11.4 (11.4) 2.4–15.5	5.91 (6.8) 0.9–9.8	$p \leq 0.0001$
Control ( $n = 20$ )	21.7 (12.6) 12.6–28.3	21.6 (20.1) 8.6–27.6	21.0 (17.6) 10.2–25.4	NS
Significance between groups	NS	$p = 0.009$	$p \leq 0.0001$	

Values are means (SD) and 25–75 percentiles, respectively.

group ( $p = \leq 0.0001$ ) one year after discharge from the hospital.

All the conclusions remained the same when we checked the possible influence of the drop-outs with the method mentioned above. How-

ever, some of the  $p$ -values changed slightly.

All patients returned to their homes. A total of 26 out of 41 subjects were employed before the acute stroke. One year postdischarge 15 subjects were still fully or part-time employed or in

**Table 4** Life quality (NHP) subscores estimated by the patients' subjective rating

	Baseline	6 weeks	12 months	Significance from baseline to 12 months
<i>Emotions</i>				
Acupuncture ( $n = 20$ )	16.8 (18.9) 4.1–21.8	6.14 (11.86) 0.0–8.4	4.20 (8.51) 0.0–4.1	$p = 0.002$
Control ( $n = 20$ )	9.57 (11.16) 0.0–15.1	13.4 (21.4) 0.0–15.5	18.9 (22.8) 0.0–29.5	$p = 0.03$ (neg)
Significance between groups	NS		$p = 0.002$	
<i>Sleep</i>				
Acupuncture ( $n = 20$ )	31.4 (36.0) 0.0–73.4	14.1 (18.5) 0.0–19.6	5.59 (10.65) 0.0–5.6	$p = 0.05$
Control ( $n = 20$ )	24.6 (29.4) 0.0–38.0	36.2 (34.3) 0.0–60.0	23.2 (28.1) 0.0–39.0	NS
Significance between groups	NS		$p = 0.01$	
<i>Physical movement</i>				
Acupuncture ( $n = 20$ )	69.7 (23.5) 57.0–86.1	26.4 (24.7) 10.2–43.3	14.4 (16.6) 0.0–24.5	$p \leq 0.0001$
Control ( $n = 20$ )	60.3 (22.8) 49.2–76.6	39.6 (30.4) 15.9–59.8	33.6 (21.3) 19.4–51.3	$p = 0.02$
Significance between groups	NS		$p = 0.0007$	
<i>Social isolation</i>				
Acupuncture ( $n = 20$ )	10.1 (22.3) 0.0–5.6	9.61 (24.63) 0.0–0.0	6.67 (14.25) 0.0–0.0	NS
Control ( $n = 20$ )	16.8 (20.1) 0.0–42.1	15.3 (24.1) 0.0–24.6	15.5 (24.3) 0.0–25.1	NS
Significance between groups	NS		NS	
<i>Pain</i>				
Acupuncture ( $n = 20$ )				
No pain	7 (35%)	13 (65%)	16 (80%)	NS
Some pain	13 (65%)	7 (35%)	4 (20%)	
Control ( $n = 20$ )				
No pain	7 (35%)	9 (45%)	10 (50%)	NS
Some pain	13 (65%)	11 (55%)	10 (50%)	
Significance between groups	NS		NS	
<i>Loss of energy</i>				
Acupuncture ( $n = 20$ )				
No loss of energy	70%	85%	100%	$p = 0.009$
Some loss of energy	30%	15%	0%	
Control ( $n = 20$ )				
No loss of energy	90%	85%	65%	$p = 0.007$ (neg)
Some loss of energy	10%	15%	35%	
Significance between groups	NS		$p = 0.008$	

**Table 5** Nottingham Health Profile (NHP II) estimated by the subjective rating scores for the stroke patients in the acupuncture study

	NHP II			Significance from baseline to 12 months
	Baseline	6 weeks	12 months	
Acupuncture	60.0 (28.4) 31.7–85.7	55.0 (26.3) 42.9–71.4	26.4 (19.3) 14.3–42.9	$p \leq 0.0001$
Control	56.4 (29.1) 35.7–85.7	57.9 (24.7) 42.9–85.7	60.7 (25.8) 42.9–78.6	NS
Significance	NS	NS	$p \leq 0.0001$	

Values are means (SD) and 25 and 75 percentiles, respectively.

vocational training (nine out of 14 in the acupuncture group and six out of 12 in the control group, respectively) (NS). Seven out of 41 patients received a disability pension prestroke; four patients in the acupuncture group versus three patients in the control group, respectively. One year later 17 persons received a disability pension; eight in the acupuncture group versus nine in the control group, respectively.

ADL dependency in personal hygiene one year after discharge was reported in six patients in the acupuncture group versus 12 patients in the control group ( $p = 0.06$ ).

Regular physiotherapy was given one year after discharge from the hospital to 15 out of 21 patients in the acupuncture group and to 17 out of 20 patients in the control group. Speech therapy was performed in three out of 12 patients with aphasia in the acupuncture group and in four out of seven patients in the control group.

At one year follow-up, seven subjects in the acupuncture group and two in the control group had their driving licence, and an additional three patients in the acupuncture group were waiting for a practical test to get back their driving licence.

## Discussion

The principal findings of the present investigation were the highly significant differences between the acupuncture group and the controls, both in life quality, motor function, ADL and social situation one year after discharge from the hospital (Tables 1–5). The patients were randomized at the beginning of the study, without significant differences in known parameters of possible influence on the results, and all had undergone an

individually adapted multidisciplinary rehabilitation programme in an institution with optimal knowledge of stroke rehabilitation. Thus, it was surprising to find that six weeks of extra acupuncture treatment had apparently resulted in significantly better outcome, both during the treatment period and during the following year.

A review of 165 studies of the efficacy of rehabilitation methods in the treatment of hemiplegia after stroke concluded that stroke patients do benefit from expert care.<sup>14</sup> A Norwegian randomized controlled trial<sup>15</sup> evaluated the clinical outcome of treatment in a stroke unit compared with treatment in general medical wards, and concluded that 'acute care in a stroke unit may be the most effective treatment we can offer stroke patients today. In addition, the reduced need for institutional care suggests that establishing stroke units is good economy.' No single treatment method, however, has conclusively shown to be more effective than another. An examination of stroke rehabilitation and physiotherapy conducted by Ernst<sup>16</sup> concluded that 'the evidence available today suggests that it does not matter which form of treatment is chosen and that any of the available approaches will improve the patients' functional status'. The consistency of these findings may be questioned as our study, as well as the Swedish study,<sup>3,4</sup> indicate that additional acupuncture treatment does give a therapeutic benefit.

The main theory in TCM is, no matter the level of impairment, to try to assist the stroke patient to recapture a sense of the body–mind being an integrated unit. The acupuncture therapy was given according to classical Chinese medicine with an individual approach regarding TCM diagnosis and point selection. After obtaining the needle sensation (de Qi), the needles were

mainly manually manipulated, and electrical stimulation of the needles was only seldom used. Hence, our acupuncture treatment cannot be considered to be electrotherapy, which is a common treatment in stroke rehabilitation.

It is noteworthy that the significant differences remained after one year following the treatment, and especially for quality of life, considering that the total amount of acupuncture treatment time was no more than 9–12 h over six weeks. We cannot be sure that a specific effect of acupuncture caused the results. However, we find it hard to believe that nonspecific effects, e.g. extra attention and time, would alone cause such results.

According to Western medicine, possible mechanisms for stroke recovery may be neuromuscular stimulation and/or general encouraging effects of the extra therapy. Current explanations for spontaneous recovery<sup>17</sup> give little evidence that the neurones in the penumbra zone remain viable for a prolonged time after vessel occlusion, and hence, are unlikely to explain long-term recovery after brain infarction. Magnusson *et al.*<sup>4</sup> postulate that acupuncture may enhance the functional plasticity of the brain. Muscle stimulation, including acupuncture, has been shown to induce the release of transmitters and neuropeptides, and it is possible that it could stimulate trophic factors that enhance recovery.

Our study cannot give conclusive evidence that acupuncture *per se* has been the active component in the rehabilitation of stroke patients. However, six weeks extra acupuncture treatment seemed to have a positive influence on motor function, ADL, life quality and social function, both during the therapy period and during the following year. Our results indicate strongly that even stroke patients with a comprehensive rehabilitation programme have an additional rehabilitation potential, and that the present treatment has proved to be one possible method of influencing this effect.

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