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# Evaluating the efficacy of acupuncture in defined aspects of stroke recovery A randomised, placebo controlled single blind study

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## Introduction

Stroke is a disease with a major socio-economic impact accounting for 10-12% of all deaths in industrialised countries; 88% of victims are over the age of 65 and it is the third most common cause of death in the UK [9].

Clinical studies of acupuncture as an adjunct to stroke rehabilitation have been encouraging, in spite of the fact that the mechanisms underlying this therapeutic approach are speculative [5]. Controlled studies [13, 16,23], and uncontrolled evaluations, including the pilot

Abstract Objective To investigate the efficacy of acupuncture on stroke recovery compared to an inert placebo. Design Placebo-controlled, randomised, clinical trial. *Setting* Post-stroke rehabilitation wards in five NHS hospitals in the UK. Subjects Patients between 4 and 10 days after their first stroke. Interventions and outcome measures The patients received 12 acupuncture or placebo treatments over four weeks. Acupuncture with electrical stimulation was compared with mock TENS, and assessments continued for 12 months after entry. Primary outcome was the Barthel Index (BI). Secondary outcomes were muscle power, Motricity Index (MI), mood, Nottingham Health Profile (NHP) and treatment credibility. Results 92 patients completed data sets. Data were analysed using both t tests and a structural equation based on longitudinal analysis of both BI and MI, using generalised estimating equations with an exchangeable correlation structure. While both acupuncture and placebo (mock TENS) appeared to have had an equal effect on stroke recovery, there is no significant difference between the two interventions at 12 (p = 0.737, 95% CI - 2.00 to 2.81)and 52 weeks (p=0.371, 95 % CI -3.48 to1.32). An apparently accelerated improvement in the MI scores in the acupuncture group at 3 weeks (p = 0.009, 95 % CI 1.55 to 10.77) is interesting. Conclusions Acupuncture did not demonstrate specific efficacy over placebo and both groups did as well as normally expected with this condition.

■ **Key words** acupuncture • stroke • rehabilitation • randomised controlled trial • placebo

study for this protocol [6, 12, 24], suggest significant differences in outcome between routine post-stroke care plus acupuncture and routine care alone. A recent systematic review [27] suggested that acupuncture may have a small positive effect on motor disability, justifying further research. As one fifth of UK physiotherapists now use acupuncture [12], and many are directly involved in stroke rehabilitation, there is interest in evaluating this therapy. Many previous acupuncture and stroke trials have been of poor quality, including patients with Transient Ischaemic Attacks (TIAs) [8, 16], or involving only manual acupuncture, [6] whereas electro-acupuncture is quite commonly used as a standard Chinese stroke treatment modality [13] and used by UK physiotherapists. Since no previous studies have utilised an inert placebo/control it is not clear whether the therapeutic effect observed was due to the efficacy of the acupuncture or other, as yet ill-defined, non-specific therapeutic effects associated with acupuncture treatment [22].

Previous studies being equivocal, we planned a single blind, two-armed randomised controlled trial to evaluate the effects of adjunctive acupuncture versus placebo in patients receiving a standardised protocol of stroke rehabilitation. Primary outcome was the Barthel Index (BI) at 12 weeks and our specific hypothesis was that acupuncture would have an effect on stroke recovery. A further hypothesis that acupuncture would have a greater effect on those patients with greater neurological deficit suggested by Hu's work [13], prompted stratification into 2 sub-groups using the BI scores. The study period for each patient was one year, involving 4 weeks of treatment and 48 weeks of follow-up evaluation.

## Method

#### Subjects

The study was carried out in 5 general hospitals in Hampshire (UK) between 1998 and 2002. Ethical approval was obtained and patients were enrolled after informed consent was obtained. Patients consented to receive one of two interventions. They were informed verbally and in writing that neither might have any effect on their condition. Patients of all ages and both sexes were eligible with an acute stroke 4–10 days before randomisation, demonstrating more than a 25% deficit on MI. Exclusion criteria were: previous stroke or TIA, inability to provide informed consent, serious co-morbidity, cardiac pacemaker, current participation in other studies, continued cerebral bleeding on CT scan.

#### Randomisation and blinding

Since a BI of 8 or less is known to represent severe disability [26], randomisation to acupuncture or control intervention was computer generated by independent administrative staff in blocks of six. These were then stratified into two sub-groups, using the BI score on entry; to control for severity as a potential covariate of treatment outcome, (less severe (BI 9–20) and more severe (BI 0–8)).

The treatment codes were placed in sealed opaque envelopes which were distributed to participating wards. The decoding lists were kept secure centrally by clerical staff.

The patients were not blinded to their treatment allocation and the ward staff were told that two equally effective interventions were being evaluated. The assessment nurses were blinded to the patient treatment group. They were told not to discuss treatment with the patients and the patients' allocation was not recorded in their case records. A short questionnaire was evaluated for treatment credibility [4] as a surrogate for testing patient blinding.

#### Interventions

Treatment began 4–10 days after the stroke. Each treatment session was 30 minutes in duration, with the patient supine, and occurred three times a week for four weeks (12 treatments). Treatments were completed in the patients' homes if they were discharged within four weeks. All patients received prescribed drug therapy, routine physiotherapy and occupational therapy throughout; this was "usual care" ordered by blinded healthcare staff.

All physiotherapists were employed by the participating hospitals, and normally worked on the stroke wards. They received specific Acupuncture Association of Chartered Physiotherapists acupuncture training to ensure uniformity both in the acupuncture and the placebo TENS intervention application. The treatments were fully documented in accordance with the STRICTA [19] and good clinical practice guidelines (GCP). All acupoints were located according to the State Standard of the People's Republic of China [25].

*Group 1* received the placebo intervention. Body and scalp points were attached to TENS machines with red flashing lights and deactivated leads so that no current could flow. This was chosen because placebo needles were not available when the study was initiated and in any event would have been extremely difficult, if not impossible to use for some of the indicated body and scalp acupuncture points.

The adhesive electrodes were lightly placed on:

Upper limb: LI 10 and SJ 5.

Lower Limb: GB 31 and GB 34.

Scalp: two points at the superior and inferior ends of the motor line [14].

*Group 2* received acupuncture. Single use, sterile disposable needles of 40, 25 or 13 mm length were used, the latter being used only on the scalp. All of the available acupuncture and stroke studies were reviewed prior to this study and best practice guidelines were defined from this information. The following points were needled:

**Upper Limb:** LI 4, LI 10, LI 15 and SJ 5 with optional use of GB 20.

Lower limb: GB 31, GB 34, GB 38 and GB 43 with optional use of St 36.

Needling sensation, "Deqi" was obtained at each point, when possible. Depth of needling was according to the State Standard of the People's Republic of China [25]. Electro-acupuncture was also used with a current of 2 Hz applied to LI 10, SJ 5, GB 31 and GB 34 obtaining a slight twitch. The optional point GB 20 was used to expel the traditional Chinese pathogen "Wind" if the patient showed continuing symptoms, and the point ST 36 was used at the discretion of the physiotherapist to assist the general recovery process in the later stages of treatment [2].

*Scalp*: 4 needles were inserted at the superior and inferior ends of the motor line and at the junctions between the upper and lower limb and the head and upper limb sections. A current of 100 Hz was applied to the needle at each end, increasing until the patient felt tingling or warmth locally.

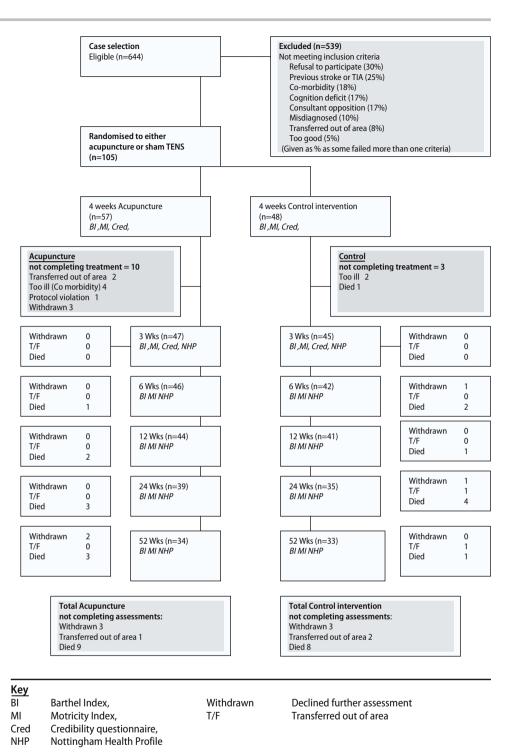
The body acupuncture was in accordance with best practice for stroke sequelae [2], and the scalp acupuncture was also given according to the standard guidelines [14].

Any side effects of either of the interventions were recorded as adverse events.

#### Outcome measures

The primary outcome measure, the 10 question, 20 point version B I at 12 weeks was used to indicate the degree of independence in Activities of Daily Living (ADL) achieved by the patients [1]. The Motricity Index (MI) was used to measure motor recovery, being a measure of muscle power based on the Oxford scale [30]. The Nottingham

## **Fig. 1** Patient flow through study (Consort) diagram



Health Profile (NHP) is a self-assessed quality of life measure, used to evaluate pain and mood [7]. If necessary, assistance (explanation only) with the completion of the NHP could be given by the assessment nurse. All outcomes were previously validated for use in stroke and were appropriate to this patient group. BI and MI assessments were recorded at baseline (entry) and at 3, 6, 12, 24, and 52 weeks. The NHP was recorded at 3, 6, 12, 24 and 52 weeks.

A short questionnaire, with a Likert like scale, adapted from Borkovec and Nau [4], was used after randomisation but before treatment and at 3 weeks post treatment to establish the perceived credibility of the two interventions (patient equipoise).

- The questions asked prior to treatment and after 3 weeks were:
- 1. How logical does this type of treatment seem to you?
- 2. How confident are you that this treatment could improve the symptoms of stroke?
- 3. Would you recommend this treatment to a friend suffering from stroke?

Three answers were available to the patients each time, "Very logical/confident", "Logical/confident" and "Not at all" in questions 1 and 2 and "Yes", "Maybe", "No" in question 3.

The post stroke domicile of the patient was recorded in the CRF by the assessment nurses each time there was a change.

#### Power calculation and statistical methods

The original power calculation indicated that 100 patients in a parallel group study should be sufficient to detect a difference of 4 units in mean B I with 80% power and 5% significance level using ANCOVA. Utilising a more powerful (and post hoc) longitudinal analysis with STATA and including all available data over baseline, 3, 6 and 12 weeks, a study with 100 patients would have an 80% power to detect a treatment difference of 2 units, at 5% significance.

The Chi-squared test and t-test were used to compare the demographic characteristics and credibility results. A t-test for independent samples and univariate analysis of variance were used to analyse the primary outcome results, BI, and the secondary measure MI. NHP was evaluated with t tests alone.

Longitudinal analysis of the outcomes was also undertaken, and applied using a random effects model with exchangeable correlation. This type of recently available analysis using generalised estimating equations, as implemented in STATA, takes account of the repeated measures nature of the data, using all available within-patient measurements to obtain maximum power.

## Results

A total of 644 patients were approached after identification by ward staff. 539 not meeting the inclusion criteria were excluded, mainly because of previous stroke or TIAs, (25%) co-morbidity (18%) or cognition deficit (17%). 9 refused to participate. A total of 105 were entered into the study and stratified, however, only 67 completed the final analysis at 52 weeks.

The majority of patients, 68 %, were recruited in the main Southampton hospital. The stratification by baseline Barthel scores was not originally analysed separately since the numbers in the 9–20 group were too few to give useful data. (BI 0–8, 77: BI 9–20, 28)

The baseline variables were equally distributed across the two treatment groups.

There were no adverse events caused by the two interventions during course of the study. One patient who was on anti-coagulants was dropped before acupuncture treatment at the beginning of the study because general bruising from handling was considered too se-

<b>Table I</b> Baseline characteristics	Table 1	Baseline characteristics
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	Acupuncture n = 57	Sham TENS n = 48
CVA (right side)	29 (47.5 %)	32 (52.5 %)
Gender male	19 (20.7 %)	26 (28.3 %)
Urine continent on entry	21 (44.7 %)	23 (51 %)
Mean age (range)	70.51 (42 to 93)	74.40 (61 to 93)

vere by the researcher. He was included in the "too ill" list.

Both interventions appear to have been credible. On entry to the study, all patients commented that their assigned intervention was "logical for their condition" (72% and 68%, "Very logical", 28% and 32% "Logical", for acupuncture and control respectively). All patients expressed "Confidence" in the treatment they received. (48% and 52%, "Very confident", 48% and 52%, "Confident").

On repeating the credibility questionnaire after nine treatments, there were no significant differences between the two groups.

#### Primary outcome measure – Barthel Index (BI)

The mean BI score for the acupuncture group on entry was a whole point lower than the control group (BI range 0–20). The mean difference between the acupuncture and control groups at 12 weeks was 0.41 (p = 0.737, 95% CI –2.00 to 2.81). The difference between BI mean scores diminished over time with the acupuncture group higher than the placebo group at 52 weeks but never reaching a statistically significant difference between treatments. Both groups improved relative to baseline but there were no significant differences between the two groups.

A post hoc division of the Barthel Index into two categories was undertaken, using scores of 0–12 and 13–20 as in the recent Cochrane review [36].

At baseline 89% of the control patients and 93.4% of those randomized to acupuncture had BI scores less than or equal to 12. Only 8 patients of the 92 scored BI higher than 12. At 12 weeks, both treatment groups showed that nearly half (48.9%) had BI scores in the higher category (applying an intention to treat analysis in which those patients who dropped out are counted in the non-responder category, i.e. BI = 0-12).

After treatment, 17 of the control patients and 20 of the acupuncture patients increased their BI scores to move from the lower to the higher BI category, while all 8 of those with the higher score at baseline increase their

	Acupuncture		 Placebo			
Time point	n	Mean BI	SD	n	Mean Bl	SD
Baseline	47	5.9	3.97	45	6.9	3.98
3 weeks	47	9.6	5.58	45	10.1	6.01
6 weeks	46	11.7	5.61	41	12.1	5.81
12 weeks	44	12.9	5.51	41	13.3	5.63
24 weeks	41	15.3	4.72	35	15.9	5.10
52 weeks	34	16.3	4.30	33	15.2	5.48

n number of patients in group at each time point; SD standard deviation

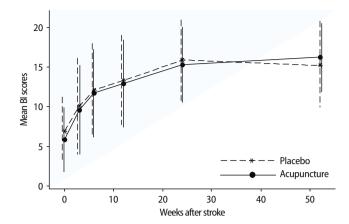


Fig.2 Graph showing mean BI scores with SD bars at baseline, 3, 6, 12, 24 and 52 weeks

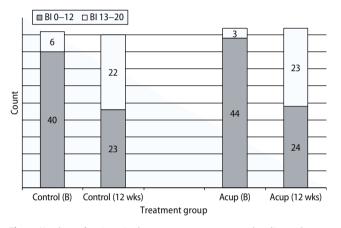


Fig. 3 Numbers of patients in the two treatment groups at baseline and at 12 weeks with BI dichotomised by dependency

BI scores within the higher category, 7 of them to the highest score of 20.

#### Motricity Index (MI)

MI scores were averaged from the totals of the upper and lower limbs scores; a higher score meaning greater muscle power. A difference between the group means of 11.4 at entry indicates that the acupuncture group was more disabled at randomisation (mean score in placebo group = 40.20, acupuncture = 29.15). The differences become insignificant at 3 weeks, indicating the possibility of an accelerated recovery in the MI for those receiving acupuncture. As with the BI, both treatment group means improved, when assessed using independent t tests, without any significant difference between the two groups from 3 weeks onwards.

#### Longitudinal analysis of BI

The longitudinal analysis of BI shows that baseline BI is a highly significant predictor of outcome as are age and urinary incontinence at entry to the study. Laterality, gender and treatment group are not significant predictors of outcome, but week post-treatment is highly significant, suggesting a curved relationship with time.

#### Longitudinal analysis of MI

This shows that MI at entry is a significant predictor of outcome, together with urinary incontinence, but age, gender and laterality are not significant. There is an apparent effect of treatment group, evidently due to the reduction in the difference between the treatment group means (only 1 or 2 units from week 3 onwards) relative to the initial baseline difference of 11.4 units.

 Table 3
 Longitudinal analysis of Bl using Generalised Estimating Equations (GEE)

 with an interchangeable correlation structure

	Coefficient	95 % Con	fidence interval	р
BI base	0.78	0.58	0.99	< 0.001
Laterality	-0.063	-1.34	1.21	0.92
Age	-0.068	-0.132	-0.005	0.035
Gender	-0.73	-1.97	0.51	0.25
Urine incontinence	-2.80	-4.447	-1.17	0.001
Week post treatment	0.31	0.24	0.38	< 0.001
Treatment group	0.26	-1.05	1.56	0.70
Week by treatment interaction	0.024	-0.002	0.051	0.074
Week squared	-0.005	-0.006	-0.004	< 0.001
Constant	13.97	7.24	20.70	< 0.001

 Table 4
 Longitudinal analysis of MI using Generalised Estimating Equations (GEE)

 with an exchangeable correlation structure

	Coefficient	95 % Con	fidence interval	р
MI base	0.79	0.67	0.91	< 0.001
Laterality	2.75	-2.96	8.47	0.34
Age	-0.22	-0.50	0.06	0.13
Gender	-3.20	-8.67	2.28	0.25
Urine incontinence	-7.74	-13.71	-1.76	0.01
Week post treatment	1.18	0.91	1.45	< 0.001
Treatment group	6.08	0.43	11.72	0.03
Week by treatment interaction	0.06	-0.038	0.17	0.22
Week squared	-0.017	-0.021	-0.013	< 0.001
Constant	37.18	12.99	61.38	0.003

#### Nottingham Health Profile (NHP)

The Nottingham Health Profile sub-scores (pain, energy levels, emotional reaction, sleep, social isolation and physical activity) were each analysed with a longitudinal analysis. A higher score in each category indicates improvement. The mean sub-scores are shown in Table 5 for each of the time points from week 3 to week 52

## Pain

The data show a significant downwards trend in pain scores (week coefficient = -0.27, 95 %CI -0.37 to -0.16) but no difference between treatments (treatment coefficient = 2.07, CI -4.71 to 8.85). Urinary incontinence is a highly significant covariate with incontinent patients scoring an average of 11 points higher for the Pain category (coeff = 11.07, CI 4.24 to 17.91).

#### **Energy levels**

These showed roughly similar scores at week 3 but those for the placebo group tend to reduce over time to about 35, whereas the scores in the acupuncture group remain at about 46. There was a significant treatment effect (treatment coeff = 11.8 p = 0.043, CI 0.35 to 23.29) with the acupuncture group having more energy.

## **Emotional reaction**

There is a downwards trend, but this does not appear to be linear, with no significant differences between treatments.

### Sleep

These scores show a significant downwards, curved trend with no significant treatment difference.

#### **Social isolation**

There was no significant difference between interventions.

47.1 (34) 36.2 (33)

863

#### Physical activity

These scores decreased for both groups in a non-linear manner with no significant difference.

## Discussion

Patients receiving acupuncture failed to show any additional improvement in our primary outcome variable, disability as measured by the Barthel Index. The actual treatment difference observed in the longitudinal analysis of BI was 0.4, which translates into a difference of about 3 % of Barthel Index at 12 weeks. The study was sufficiently powered to detect a difference of 2 units (assumed to be a change in BI of clinical importance), utilising a longitudinal analysis.

This confirms, in conjunction with the information now available from other recent published studies and systematic reviews [21, 27], that acupuncture is unlikely to have a specifically therapeutic efficacy for strokes. Covariates that normally predict stroke outcomes such as persisting urinary incontinence and increased age also did so in this study, thus supporting its generalisability in relation to the particular stroke patients recruited [18].

A baseline criterion of motor impairment was not used as such, but the degree of motor impairment had to be more than 25% in the Motricity index, an outcome measure based on the Oxford scale of muscle power. Those patients designated "too good" in the CONSORT diagram fell into this group. The apparent parity between right- and left-sided hemisphere strokes supports the conclusion that language dysfunction was not a major confounder.

Dropout or attrition bias could theoretically have been an issue, although the reasons for dropout and the final numbers analysed were not substantially different between the groups (Fig. 1). An intention to treat analysis was carried out with dropouts handled by carrying the last BI value forward. However the results were very similar to those included elsewhere in this paper.

The BI result over 12 and 52 weeks was comparable

18.2 (34) 21.6 (33)

Physical activity

Ac

PI

48.1 (47) 51.5 (45)

39.9 (46) 41.3 (41)

37.2 (44) 43.7 (41)

31.8 (41) 34.0 (35)

25.9 (34) 32.4 (33)

Week Pain Energy level **Emotional reaction** Sleep Social isolation PI PI PI PI PI Ac Ac Ac Ac Ac 3 26.9 (47) 22.1 (45) 45.4 (47) 36.6 (45) 44.5 (47) 43.9 (45) 45.0 (47) 44.5 (45) 35.5 (47) 26.7 (45) 6 23.6 (46) 20.1 (41) 46.5 (46) 36.3 (41) 39.0 (46) 30.0 (41) 40.9 (46) 34.0 (41) 26.4 (46) 19.8 (41) 12 21.5 (44) 22.8 (41) 46.3 (44) 35.2 (41) 44.1 (44) 30.6 (41) 40.5 (44) 33.9 (41) 26.4 (44) 12.2 (41) 24 17.5 (41) 19.3 (35) 49.8 (41) 31.6 (35) 35.7 (41) 26.2 (35) 15.6 (35) 21.6 (35) 31.2 (41) 18.8 (41)

31.7 (34) 30.0 (33)

25.9 (34) 32.4 (33)

Table 5 Mean scores for subsections of Nottingham Health Profile

() n; Ac acupuncture; Pl placebo

16.1 (34)

52

6.9 (33)

both with that expected from normal stroke rehabilitation and that observed in recent studies and systematic reviews [8, 15, 21, 27, 28]. This suggests that not only does acupuncture have no specific efficacy over placebo, as reported in our study, but it may also have no contextual or nonspecific benefits over conventional stroke management. Therefore the recent suggestions made by Paterson and Dieppe [22], and Kaptchuk et al. [17], that the provision of acupuncture provides an acupuncture specific beneficial "contextual" effect, or an enhanced placebo effect, are not sustained by data from this study on stroke. Two recent publications have come to similar conclusions about the clinical effect of acupuncture on stroke [15, 28].

It is debatable whether the currently available placebo needles are indeed genuine placebos. No other stroke studies report the use of a well validated, credible and entirely inactive placebo intervention such as that employed in this clinical trial. We also believe that the marginal benefits of acupuncture on stroke reported by Park et al. [21] and Wayne et al. [31] (including the minor improvement in lower limb MI score reported by Park) are not confirmed by our data.

The only clinical effects revealed in this trial were minor changes in secondary outcome measures. The acupuncture was consistent with normal practice for stroke sequelae [2], generalisable with regard to current UK practice and with no recorded serious adverse events. The control intervention was accepted as credible by patients entered in both treatment groups, as well as having been validated in a number of previous clinical trials [32, 34]. There are no differences between patient groups at entry that appear to be significant confounders of final outcome.

There is a possibility that the placebo could have had a slight acupressure effect, although there is no research evidence to support that. The TENS electrodes used did not need any pressure to make them stick, being coated with an adhesive gel and attaching themselves to the skin very readily. There are no studies clearly establishing a difference between (acupuncture) placebo techniques and the natural history of stroke recovery.

The MI shows a small effect, where the BI does not, perhaps because increases in fine motor ability may not affect the BI, since it is designed to measure overall handicap, not individual motor movements. When other factors affecting recovery as well as the difference in the initial group scores are accounted for, the longitudinal analysis demonstrates a treatment effect for MI between baseline and three weeks post treatment. This may actually be due to the effect of electrical stimulation rather than actual needling as these two interventions were not separately evaluated in this study. Electrical stimulation to muscle tissue causes a twitch or contraction and a change in the micro-circulation and therefore may provide the mechanism for an improved MI [3, 29, 33]. A further study, looking at the same type of electric stimulus applied at acupuncture and non-acupuncture points might resolve this question and perhaps could also confirm whether the acupuncture normalises muscle tone as claimed by Yu [35].

The longitudinal modelling of the NHP showed no important differences between groups. However, the energy levels in the acupuncture group remained higher than placebo and were significantly better 6 weeks after the treatment period. Perhaps patients who scored lower in the NHP categories had more insight into their condition, affecting their self-assessment. This, although speculative, is of interest since the acupuncture group seemed to have been lower scorers in all categories. Better psychosocial functioning is found in groups of braininjured patients who do not use the strategies of "wishful thinking" and "avoidance" [20], so perhaps a more realistic attitude helped these patients and this appears to be loosely associated with acupuncture treatment. There is some evidence from this study that a greater percentage of patients in the acupuncture group are able to continue living in their own home after treatment, but the mechanism for this remains unclear. This observation was also noted in a recent Cochrane review using the data available from other studies [11, 36].

Acupuncture may, through the modulation of neurotransmitters, have an influence on emotional well-being and coping strategies. This may be long lasting but the mechanism underlying its durability is unknown, in the same way that the mechanism underlying the effect of acupuncture in the treatment of pain is also unknown [10]. Sze's conclusion that acupuncture demonstrates a small positive effect on disability may be supported in part by this [27].

The dropout rate was high, a high rate of general comorbidity and death was anticipated, since those patients only mildly disabled by their stroke (none below 25% impairment in the MI scale) were deliberately excluded. The number of patients transferred outside the area to be with their families was not anticipated however. This study was run according to GCP standards current at the time. No reasons were given for the three withdrawals during the acupuncture treatment period. Had they been reported as adverse reactions by the patients or practitioners this would have been investigated. As they were not, we feel it is reasonable to state that there were no adverse events caused by either of the two interventions during the course of the study. Acupuncture used in the treatment of acute stroke would thus appear to be relatively risk free, although this study was not designed to specifically test safety.

This study was potentially underpowered; partly because of the rigorous exclusion criteria and our decision not to include patients with previous strokes and TIAs.

Serious recruitment problems were experienced for various reasons, primarily due to a major re-organisa-

tion of stroke care in the hospitals involved. Consequently the trial closed prematurely but the longitudinal analysis, with the numbers that were recruited, gave the power to detect a clinical treatment difference of 15%, at 5% significance.

Any conclusions that we have drawn should therefore, necessarily, be treated with caution. However, taking into account all the data now available, there seems to be little to be gained from further large studies evalu-

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ating acupuncture as an adjunctive or complementary therapy for stroke patients.

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