ACUPUNCTURE FOR POST-STOKE REHABILITATION

HEALTH TECHNOLOGY ASSESSMENT SECTION
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MINISTRY OF HEALTH MALAYSIA

05/2015

DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia

EXECUTIVE SUMMARY

Background

Acupuncture is one of the main modalities of treatment in traditional Chinese medicine for more than 2,000 years and its use for post-stroke rehabilitation in China is based on a large body of preclinical and clinical research. It is claimed that being a relatively simple, inexpensive and safe treatment compared to other conventional interventions, acupuncture has been well accepted by Chinese patients and is widely used to improve motor, sensation, speech and other neurological functions in patients with stroke. As a therapeutic intervention, acupuncture is also increasingly practiced in some Western countries. The lack of English language publications has, however, impeded any serious consideration of acupuncture as a treatment for post-stroke rehabilitation and it remains uncertain whether the existing evidence is scientifically rigorous to be recommended for routine use.

This technology review was conducted following a request from the Director of Traditional and Complementary Medicine (T&CM) Division, Ministry of Health Malaysia, to provide the available evidence for ensuring T&CM practice in Malaysia is safe and conforms to acceptable standards for the benefits of the public, and in line with the requirement of the Traditional and Complementary Medicine Act 2013.

Objective/aim

The objective of this technology review was to review evidence on the effectiveness, safety and cost-effectiveness of acupuncture therapy in post-stroke rehabilitation patients.

Results and conclusions

A total of 32 titles were identified through the Ovid interface and PubMed. Eight articles related to acupuncture for post-stroke rehabilitation is included in this review: six systematic review and meta-analysis, and two randomised controlled trials. The studies were conducted in United Kingdom, United States, China, Taiwan, Hong Kong, Korea, Germany, Norway, and Sweden.

There was high level of evidence on the effectiveness of acupuncture for post-stroke recovery. However, the included trials in most of the systematic reviews have biases due to inappropriate randomised sequence generation, lack of allocation concealment, inadequate level of blinding, poor description of patient withdrawals from the studies and the adverse events and hence, varying the quality of the included trials. Nevertheless, findings from the systematic reviews showed that:

1. Acupuncture seemed to be superior to conventional treatments or provide added value in terms of:

- Improvement in global neurological deficit [odds ratio (OR)=6.55; 95% confidence interval (CI): 1.89 to 22.76]
- Improvement in motor impairment scales, generalized stroke scales, and disability assessment (OR=4.33; 95% CI: 3.09 to 6.08)

2. Scalp acupuncture (SA) seemed to be effective as an adjunct treatment to the conventional care (medication or rehabilitation) in terms of:

   i. Total efficacy rate:
   - SA plus medication versus medication: [risk ratio (RR)=1.19; 95% CI: 1.05 to 1.36]
   - SA plus rehabilitation versus rehabilitation (RR=1.12; 95% CI: 1.01 to 1.23)

   ii. Activities of daily living (Barthel Index)
   - SA plus medication versus medication: [standardized mean difference (SMD)=0.78; 95% CI: 0.40 to 1.17]
   - SA plus rehabilitation versus rehabilitation [weighted mean difference (WMD)=13.41; 95% CI: 11.05 to 15.76]

   iii. Changes in neurological function (Neurological deficit score)
   - SA plus medication versus medication: (SMD=-0.61; 95% CI: -0.81 to -0.40)

3. Electro-acupuncture could be effective in decreasing post-stroke spasticity (Weighted mean difference 0.72; 95% CI: 0.29 to 1.14; $p<0.001$) compared with usual care or placebo.

4. Acupuncture treatment plus rehabilitation was superior compared with only rehabilitation for the recovery of apoplectic hemiplegia in terms of:

   - Improvement motor function ($p<0.05$)
   - Improvement activities of daily living ($p<0.05$)

5. Acupuncture-massage therapy may have curative effects on shoulder-hand syndrome in hemiplegia patients compared to rehabilitation group in terms of:

   - Improvement in numeric pain rating scale ($p<0.05$)
   - Fewer patients with shoulder-hand syndrome at Steinbrocker stage II or III ($p<0.05$)

Acupuncture seemed to be relatively safe with minimal adverse events, and there was no retrievable evidence on its cost-effectiveness. The cost per session varies according to scope of treatment ranges between RM 60 to RM 120. However, it was provided free of charge by T&CM unit in several dedicated governmental hospitals.

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - January 2015, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to January 2015, EBM Reviews - Health Technology Assessment – 1st Quarter 2015, EBM Reviews - Database of Abstracts of Reviews of Effects – 1st Quarter 2015, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2015. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 25th February 2015.

ACUPUNCTURE FOR POST-STROKE REHABILITATION

1.0 BACKGROUND

According to the World Health Organization (WHO), stroke is responsible for increasingly high rates of mortality and disability worldwide. Due to an aging population, dietary changes, and work-related stress, stroke morbidity is on the rise and the age at first occurrence is getting younger.[1] It is among the top four leading causes of death in ASEAN countries, with the crude death rate ranging from 10.9 per 100,000 in Thailand to 54.2 per 100,000 in Singapore.[2] In Malaysia, stroke was the top two leading causes of death reported by Malaysian National Burden of Disease Study. Mortality because of stroke constituted 8.9% in males and 12.1% in females of total certified deaths. Despite considerable research efforts on multiple treatment modalities, patient still search for alternative in an attempt to further improve the outcome of stroke rehabilitation, such as acupuncture.[3]

Acupuncture is one of the main modalities of treatment in traditional Chinese medicine for more than 2,000 years and its use for post-stroke rehabilitation in China is based on a large body of preclinical and clinical research.[4] It is claimed that being a relatively simple, inexpensive and safe treatment compared to other conventional interventions, acupuncture has been well accepted by Chinese patients and is widely used to improve motor, sensation, speech and other neurological functions in patients with stroke. As a therapeutic intervention, acupuncture is also increasingly practiced in some Western countries.[5, 6] The lack of English language publications has, however, impeded any serious consideration of acupuncture as a treatment for post-stroke rehabilitation and it remains uncertain whether the existing evidence is scientifically rigorous to be recommended for routine use.

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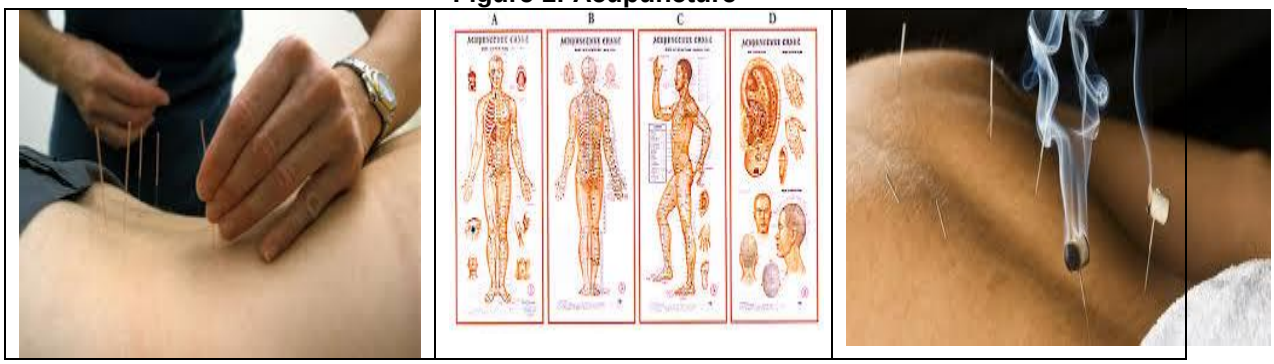
2.0 OBJECTIVE/AIM

The objective of this technology review was to review evidence on the effectiveness, safety and cost-effectiveness of acupuncture therapy in post-stroke rehabilitation patients.

3.0 TECHNICAL FEATURES

Acupuncture [from Latin, '*acus*' (needle) + '*punctura*' (to puncture)] literally means to puncture with a needle. The technique involves placing hair-thin needles in various pressure points throughout the body. Stimulating these points is believed to promote the body's natural healing capabilities and enhance its function. It can be associated with the application of heat, pressure, or laser light to these same points. There are two very different ways of looking at acupuncture; from the traditional Chinese medicine and modern international perspective. [7]

Figure 1: Acupuncture



According to Chinese philosophy, the body contains two opposing forces: *yin* and *yang*. When these forces are in balance, the body is healthy. In traditional Chinese medicine, acupuncture is linked to the belief that disease is caused by disruptions to the flow of energy in the body (called *qi*, pronounced "*chee*"). When healthy, an abundant supply of *qi* or "life energy" flows through the body's meridians (a network of invisible channels through the body). If the flow of *qi* in the meridians becomes blocked or there is an inadequate supply of *qi*, then the body fails to maintain harmony, balance and order, and disease or illness follows. This can result from stress, overwork, poor diet, disease pathogens, weather and environmental conditions, and other lifestyle factors. Acupuncture treatment involves the insertion of fine, sterile needles into specific sites (acupuncture points) along the body's meridians to clear energy blockages and encourage the normal flow of *qi* through the individual. The practitioner may also stimulate the acupuncture points using other methods, including moxibustion, cupping, laser therapy, electro-stimulation and massage, in order to re-establish the flow of *qi*.[8]

In the Western view, acupuncture likely works by stimulating the central nervous system (the brain and spinal cord) to release chemicals called neurotransmitters and hormones. These chemicals dull pain, boost the immune system and regulate various body functions.[8]

4.0 METHODS

4.1. Searching

Electronic databases searched through the Ovid interface:

- MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present
- EBM Reviews – Cochrane Central Registered of Controlled Trials – January 2015
- EBM Reviews – Database of Abstracts of Review of Effects – 1st Quarter 2015
- EBM Reviews – Cochrane Database of Systematic Reviews – 2005 to January 2015
- EBM Reviews – Health Technology Assessment – 1st Quarter 2015
- EBM Reviews - NHS Economic Evaluation Database – 1st Quarter 2015

Other databases:

- PubMed
- Horizon Scanning database (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham)
- Other websites: US FDA, INAHTA, MHRA

General databases such as Google and Yahoo were used to search for additional web-based materials and information. Additional articles retrieved from reviewing the bibliographies of retrieved articles or contacting the authors. The search was limited to articles on human. There was no language limitation in the search. **Appendix 1** showed the detailed search strategies. The last search was conducted on 25th February 2015.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Post-stroke rehabilitation
Interventions	Acupuncture, traditional body needling, moxibustion, electric acupuncture, electro-acupuncture, laser acupuncture, photo-acupuncture, microsystem acupuncture, scalp acupuncture, acupressure
Comparators	Placebo acupuncture, sham acupuncture, other conventional treatment
Outcomes	Neurologic deficit, activities of daily living, motor recovery, quality of life, adverse events
Study design	Systematic reviews (SRs), randomised control trials (RCTs), cross-sectional, cohort, case control, case series
Type of publication	English, full text articles

Exclusion criteria

Study design	Case report, survey, anecdotal, animal studies
Type of publication	Non-English

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the US/Canadian Preventive Services Task Force (See **Appendix 2**). Data were extracted from included studies using a pre-designed data extraction form (evidence table as shown in **Appendix 3**) and presented in tabulated format with narrative summaries. No meta-analysis was conducted for this review.

5.0 RESULTS AND DISCUSSION

The search strategies yielded eight articles related to the effectiveness and adverse event of acupuncture for post-stroke rehabilitation whereas none on the cost-effectiveness. Articles consists six systematic review and meta-analysis while two articles for randomised controlled trials.

5.1 Effectiveness

A systematic review by Park JB et al. 2001 searched four independent computerised literatures including MEDLINE, Cochrane Controlled Trials Register, Embase, and Centralised Information Service for Complementary Medicine (CISCOM), which includes the British Library Alternative Medicine database (AMED) in June 1999. All RCTs that compared any form of needle insertion acupuncture to any form of non-acupuncture control intervention in the treatment of human stroke patients were included. The methodological quality of the included studies was assessed using the Jadad score. Nine studies were included in the review and total number of subjects enrolled was 538, of whom 288 received acupuncture. Two studies used manual acupuncture, five electro-acupuncture, and two used both techniques. Standard medical and rehabilitative treatments or sham electro-acupuncture were used as control intervention. A range of outcome measures was used such as Scandinavian Stroke Scale, Chinese Stroke Scale or Recovery measure, Barthel Activities of Daily Living (ADL) index, Nottingham Health Profile (NHP), motor function, balance, and number of days in hospital. They found that of the nine studies, six yielded a positive result suggesting that acupuncture is effective, and three produced a negative finding implying that acupuncture is not superior to control treatment. Only two studies obtained a Jadad score of more than three, and these methodologically best trials showed no significant effect of acupuncture (**Table 1**). The authors concluded that there is no compelling evidence to show that acupuncture is effective in stroke rehabilitation.[9, level I]

Table 1: Key results of RCTs on effectiveness of acupuncture for stroke

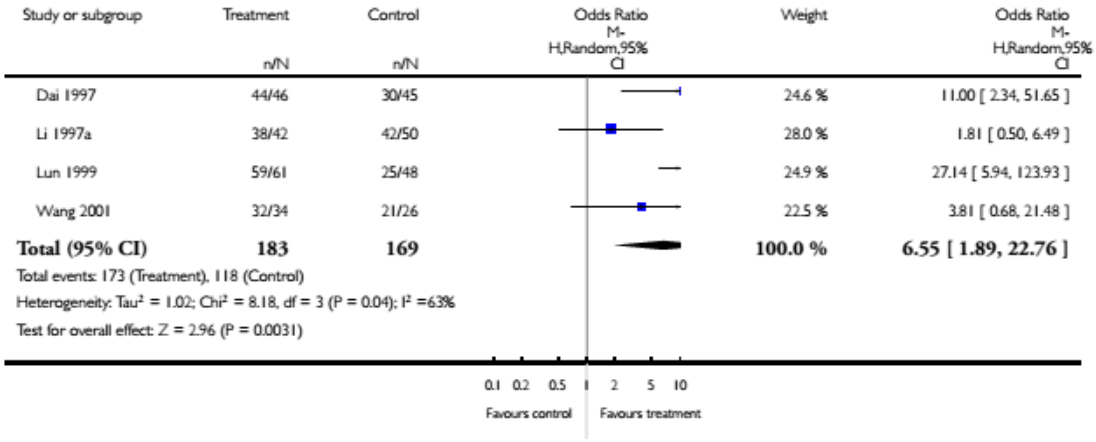
First Author	Design[1]	Primary Outcomes	Main result compared with control	Jadad score	Adverse events (No. of events)	Comment Lesion related Subgroup
Zou [31] 1990	Open	CSRM	Significant improvement ($p < 0.001$)	1	No mention	*Analysis showed significant improvement.*
Naeser [20] 1992	SB	Range of movement	No significant improvement($p > 0.05$)	3	No mention	
Johansson [14] 1993	Open	Motor function, Barthel ADL, NHP	Significant improvement ($p < 0.01$) except active movements score	2	No mention	
Hu [11] 1993	Open	SSS, Barthel ADL	SSS-significant improvement ($p=0.02$ except Barthel ADL	2	Dizziness (1)	*Subgroup analysis showed significant improvement in the poor initial neurological score.*
Sallström [25] 1995	AB	MAS, Sunnas ADL, NHP	Significant improvement ($p < 0.001$) except Sunnas ADL	2	No mention	
Zhang [30] 1996	Open	CSRM	No significant improvement ($p=0.4372$)	1	No mention	
Gosman-Hedström [7] 1998	SB, AB	Barthel ADL	No significant improvement ($P > 0.05$)	5	No mention	*Data more fully given in the follow-up study.*
Si [26] 1998.	AB	CSS	Significant improvement ($p < 0.01$)	1	No mention	
Duan [4] 1998	Open	CSRM	Significant improvement ($p < 0.001$)	1	No mention	

SB: Subject Blind; *AB:* Evaluator Blind; *MAS:* Motor Assessment Scale; *SSS:* Scandinavian Stroke Scale; *NHP:* Nottingham Health Profile; *SS:* Chinese Stroke Scale; *CSRM:* Chinese Stroke Recovery Measure; *ADL:* Activity of Daily Living

[1] All studies were prospective randomised trials with 2 or more parallel arms

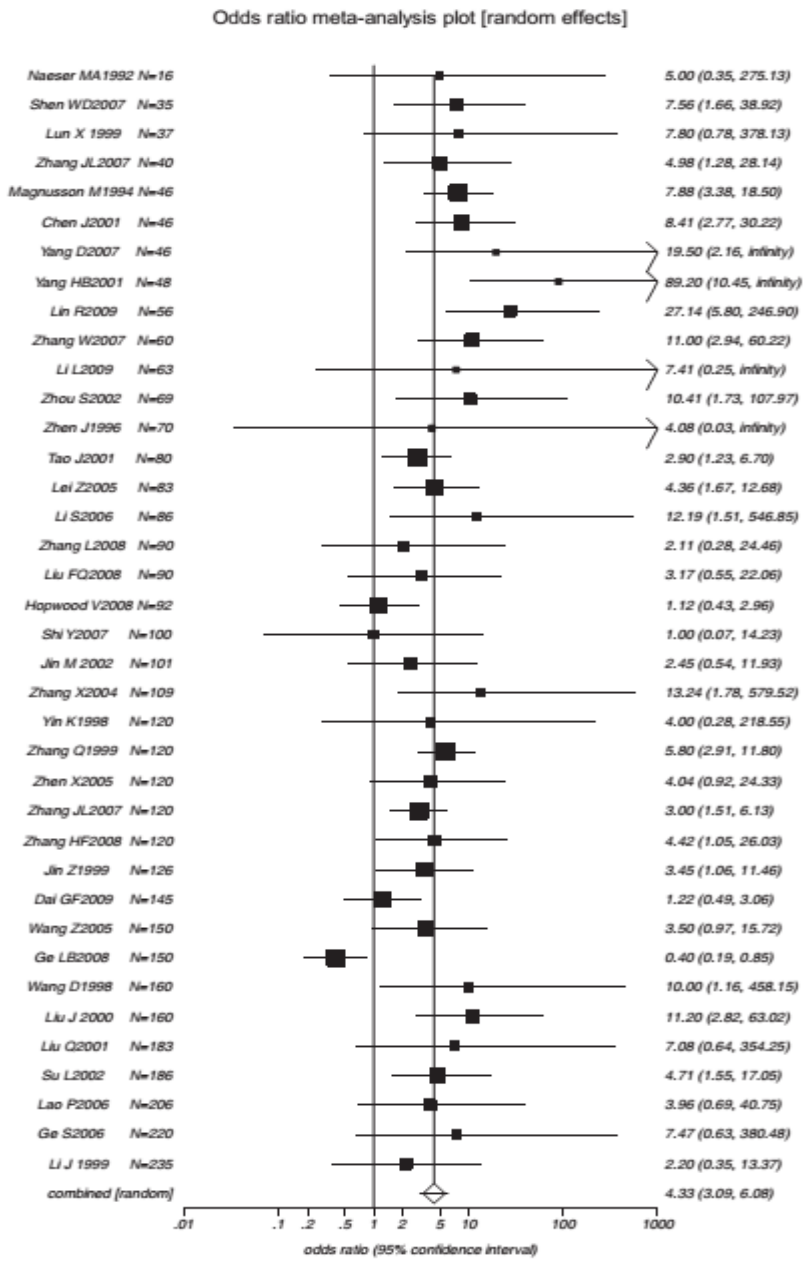
Cochrane systematic review on the efficacy of acupuncture for patients with ischemic or haemorrhagic stroke in the subacute (one to three months since onset) or chronic phases (over three months since onset) was conducted in 2006. The computer literature searches included MEDLINE, Cochrane Trials Register, Embase, CINAHL, AMED, Chinese Stroke Trials Register, Chinese Acupuncture Trials Register and Chinese Biological Medicine Database, National Center for Complementary and Alternative Medicine Register, and National Institute of Health Clinical Trials Database. They also hand searched four Chinese journals and checked reference lists of all papers identified for further trials. All RCTs comparing acupuncture with at least one control group that used placebo, sham treatment or conventional treatment were included. Fifty potentially eligible trials were retrieved. Of these, five trials including a total of 368 patients met inclusion criteria. Methodological quality was considered inadequate in all trials. No trial described the method of randomisation, and allocation concealment was unclear in all included trials. Only one trial reported that participants were blinded but did not describe the method in detail. There was no statement on dropouts or withdrawals in any of the included trials. Although the overall estimate from four trials suggested the odds of improvement in global neurological deficit was higher in the acupuncture group compared with the control group [odds ratio (OR) 6.55, 95% confidence interval (CI) 1.89 to 22.76], this estimate may not be reliable since there was substantial heterogeneity (I^2 = 68%) (**Figure 1**). One trial showed no significant improvement of motor function between the real acupuncture group and the sham acupuncture group (OR 9.00, 95% CI 0.40 to 203.30), but the confidence interval was wide and included clinically significant effects in both directions. No data on death, dependency and institutional care, change of neurological deficit score, quality of life or adverse events were available. They concluded that this SR does not provide evidence to support the routine use of acupuncture for patients with subacute or chronic stroke.[10, level I]

Figure 1: Improvement of global neurological deficit at the end of treatment



Wu P et al. 2010 conducted a systematic review and meta-analysis of all randomised clinical trials of acupuncture for post-stroke rehabilitation. They searched the following English electronic databases: MEDLINE, AMED, Alt Health Watch, CINAHL, Nursing and Allied Health Collection: Basic, and Cochrane Database of Systematic Reviews from inception to September 2009. In addition, they searched the Chinese database CNKI, CBM, and Wan Fang independently. Eligible studies included RCTs that evaluated the clinical efficacy of acupuncture in adult patients with disability after stroke compared with sham acupuncture or no acupuncture treatment. This review included 35 articles written in Chinese and 21 in English, and involved 5,650 patients; 3,156 in the treatment groups and 2,494 in the control groups. The trials used various outcome measures included motor impairment scales, generalized stroke scales, and disability assessments. In general, randomisation and allocation concealment were poorly reported. Only 25% (14/56) of the studies gave detailed accounts of how patients were randomised. A total of 12.5% (7/56) of the studies adequately reported allocation concealment. Patients were blinded in 11% (6/56) of the studies in which sham acupuncture was used as a control. Assessor blinding was reported in a total of 28.6% (16/56) studies. Positive results were reported in 45 of the 56 studies. No significant differences between acupuncture intervention and control were reported in five studies. In 38 trials, data were available for meta-analysis and meta-regression, yielding an OR in favour of acupuncture compared with controls (OR = 4.33, 95% CI: 3.09 to 6.08; I^2 = 72.4%) (**Figure 2**). Randomisation, modes of delivery, method of control, study source country, and reporting of randomisation may explain some of the heterogeneity observed between the studies. The authors concluded that acupuncture may be effective in the treatment of post-stroke rehabilitation. Poor study quality and the possibility of publication bias hinder the strength of the recommendation and argue for a large, transparent, well-conducted randomised clinical trial to support this claim and implement changes to clinical practice.[11, level I]

Figure 2: Efficacy in post-stroke rehabilitation with acupuncture compared with no acupuncture



Another systematic review and meta-analysis by Kong JC et al. 2010 critically evaluated all of the currently available randomised sham-controlled trials of acupuncture (with or without electrical stimulation) as an adjunct to mainstream stroke rehabilitation. Following databases were searched: MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycINFO, Cochrane Library (2009; issue 4), Asian journals and 12 major Korean traditional medicine journals. Ten of 664 potentially relevant studies involving 711 participants met the inclusion criteria. Seven trials

included patients in the acute or subacute stage of stroke, and three included patients in the chronic stage. Five trials used blinding of participants and assessors, three used blinding of participants only, and two used blinding of assessors only. Three trials reported details about allocation concealment. Four trials tested the effects of acupuncture on neurologic deficits using the National Institutes of Health Stroke Scale, the European Stroke Scale or the Scandinavian Stroke Scale. One of the four studies showed positive therapeutic effects. Seven trials tested the effects of acupuncture on activities of daily living according to the Barthel Index, the modified Barthel Index or the Sunaas Index of Activities of Daily Living. Two of these studies (both from China) showed favourable effects on activities of daily living. Of the five trials that assessed the effects of acupuncture treatment on quality of life, none showed favourable effects. A meta-analysis of the five studies that assessed functionality which involved patients in the acute and subacute stages of stroke did not show a significant difference in favour of acupuncture, with high heterogeneity (n=368; standard mean difference 0.47, 95% confidence interval [CI]–0.02 to 0.96; I^2 = 81%) (**Figure 3A**). A post-hoc sensitivity analysis of three trials with low risk of bias did not show beneficial effects of acupuncture on activities of daily living at the end of the intervention period (n=244; standard mean difference 0.07, 95% CI–0.18 to 0.32; I^2 = 0%) (**Figure 3B**) or after follow-up (n=244; standard mean difference 0.10, 95% CI –0.15 to 0.35; I^2 = 0%) (**Figure 3C**). For the chronic stage after stroke, three trials tested effects of acupuncture on function according to the Modified Ashworth Scale; all failed to show favourable effects. They concluded that this meta-analysis of data from rigorous randomised sham-controlled trials did not show a positive effect of acupuncture as a treatment for functional recovery after stroke.[12, level I]

Lee SJ et al. 2013 conducted a systematic review and meta-analysis to integrate the current clinical evidence and to evaluate the effectiveness of scalp acupuncture (SA) for patients with stroke in compliance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. Two independent reviewers searched the following 16 electronic databases from their inception through June 2012: PubMed, Medline, The Cochrane Library 2012 (Issue 6), CINAHL, China Academic Journal, Wanfang Med Online, nine Korean Medical Databases and the Japanese Medical Database. All RCTs that compared SA as a sole or adjunct treatment with any relevant controls for stroke were included. They found 1,811 potentially relevant studies, of which 21 publications (2,172 stroke patients) fit the criteria for inclusion. Of those 21 publications, 14 trials studied 1,634 acute or subacute stroke patients, and three RCTs studied 223 chronic stroke patients. The remaining four trials included 315 mixed-stage stroke patients. The quality of the included RCTs was generally low. Ten trials used proper random sequence generation methods. None of the included trials conducted allocation

concealment. Patient blinding was reported in only two RCTs. Furthermore, seven RCTs did not clearly describe any blinding methods. Among the 14 trials, eight used the total efficacy rate as the main outcome, and their meta-analysis showed a favourable effect on outcomes of SA plus conventional care compared to conventional care alone (medication $p = 0.007$, and rehabilitation $p = 0.02$) (**Figure 4A**). Similar favourable results were shown in the outcomes of activities of daily living (Barthel index; medication $p < 0.0001$, and rehabilitation $p < 0.00001$) (**Figure 4B**) and neurological function outcomes (medication $p < 0.00001$) (**Figure 4D**), but not in the motor function (Fugl–Meyer assessment, $p = 0.30$) (**Figure 4C**). No significant differences were shown in total efficacy rate, Barthel index, or Fugl-Meyer assessment values for sole SA compared with conventional care alone. For the chronic and mixed stages of stroke, no meaningful results were obtained. Sensitivity analysis by study quality could not be performed because of the poor methodological quality of all included trials. The authors concluded that this review showed positive but limited effectiveness of SA as an adjunct treatment to the conventional care. The major limitation was the poor methodological quality of the included trials. Sham-controlled, well-designed trials with a standardized therapeutic method are needed.[13, level I]

Figure 3: Meta-analyses of sham-controlled randomized clinical trials of the effectiveness of acupuncture for functional recovery after stroke

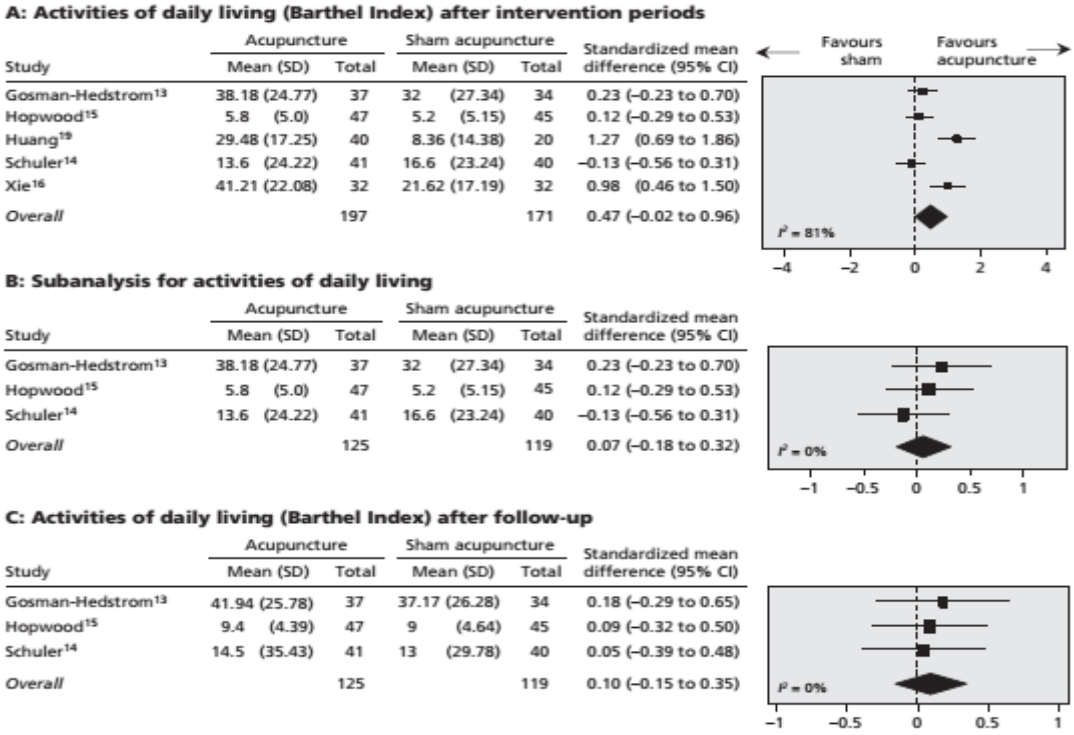
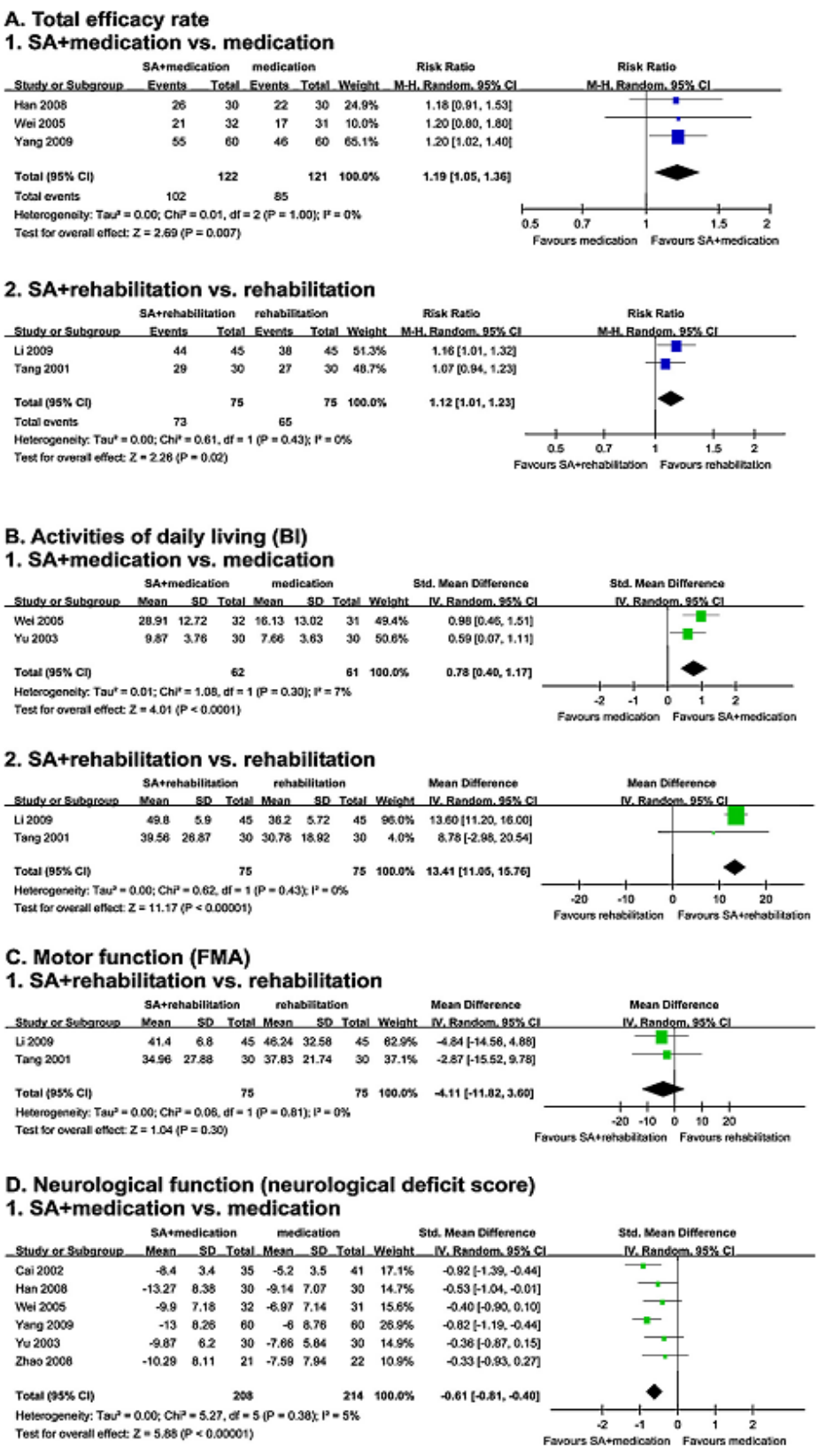


Figure 4: Scalp acupuncture for acute and subacute stroke



A current meta-analysis performed by Sung ML et al. 2014 to determine the effectiveness of acupuncture or electro-acupuncture in treating post-stroke patients with spasticity. They searched publications in Medline, Embase, and Cochrane Library, accredited journals in Korean, and China Integrated Knowledge Resources Database in Chinese through to July 2013. All RCTs that compared the effects of acupuncture or electro-acupuncture with usual care or placebo acupuncture were included. They assessed the risk of bias and statistical analysis were performed primarily with the Modified Ashworth Scale (MAS). A total of 187 publications were identified, of which five RCTs (three in English while one each in Korean and Chinese) were finally included by the eligibility criteria. Most of the studies were low quality and had methodological shortcomings, such as an inadequate level of blinding. The pooled data showed a weighted mean difference of 0.72 and 95% confidence intervals (CI) of 0.29 to 1.14 on the MAS, indicating that acupuncture or electro-acupuncture had a significant effect on decreasing post-stroke spasticity (P < 0.001). In the subgroup analysis examining the types of acupuncture, electro-acupuncture therapy significantly decreased spasticity after stroke (weighted mean difference of 0.76, 95% CI [0.25, 1.27], P = 0.004), while acupuncture therapy showed slightly, but not significantly, decreased spasticity (weighted mean difference of 0.58, 95% CI [−0.69, 1.85], P = 0.37) (**Figure 5**). The subgroup analysis based on the regions of spasticity revealed that acupuncture or electro-acupuncture significantly reduced spasticity of wrists (weighted mean difference of 0.68, 95% CI [0.03, 1.33], P = 0.04), knees (weighted mean difference of 0.70, 95% CI [0.51, 0.89], P < 0.001), or elbows (weighted mean difference of 0.74, 95% CI [0.55, 0.94], P < 0.001). There was some alleviation of spasticity of ankle region, but this was not statistically significant (weighted mean difference of 0.58, 95% CI [−0.69, 1.85], P = 0.37) (**Figure 6**). They concluded that acupuncture or electro-acupuncture could be effective in decreasing spasticity after stroke, but long-term studies are needed to determine the longevity of treatment effects.[14, level I]

Figure 5: Meta-analysis of acupuncture for spasticity after stroke

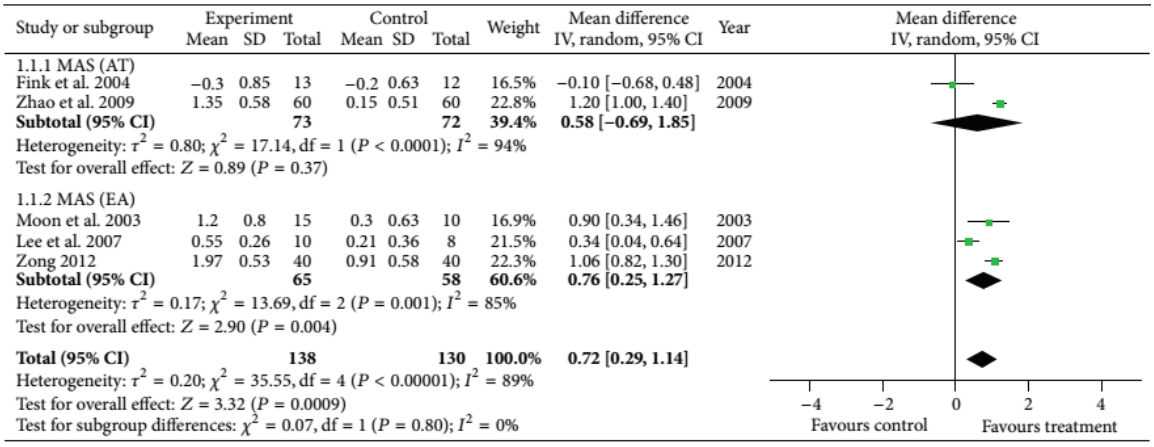
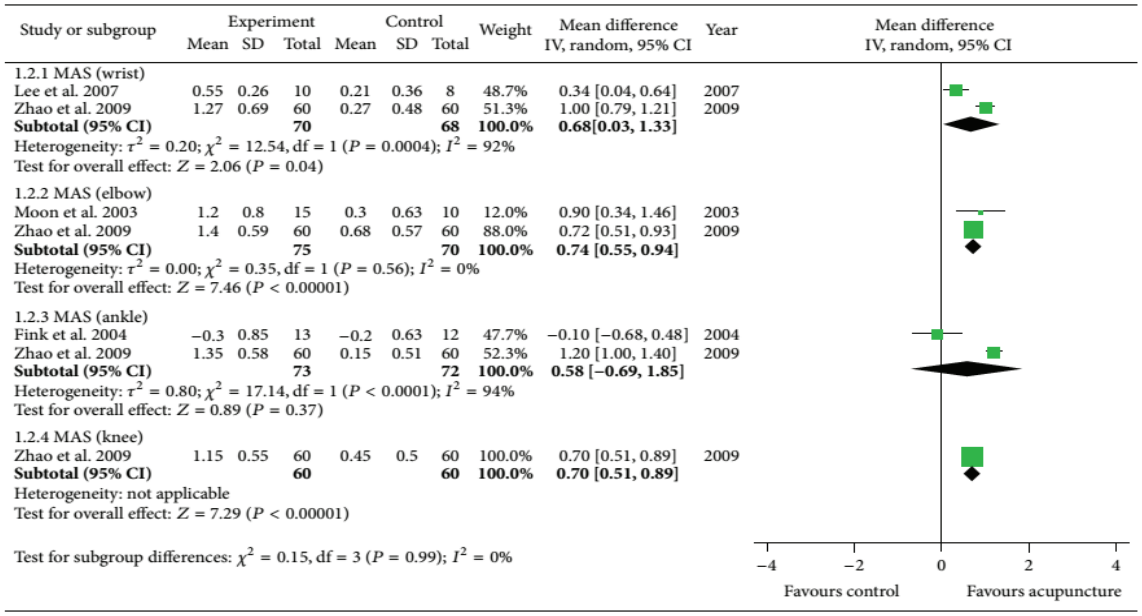


Figure 6: Meta-analysis of acupuncture for spasticity after stroke according to region



Mao M et al. 2008 conducted a RCT to evaluate the effect of stage-oriented comprehensive acupuncture treatment plus rehabilitation compared with only rehabilitation for the recovery of apoplectic hemiplegia. Sixty patients who were diagnosed as having early-stage haemorrhagic and ischemic apoplectic hemiplegia were divided randomly into the treatment and control groups with 30 in each. Before and three months after treatment, the evaluation was done on the motor function and daily life ability for both groups respectively with simplified Fugl-Meyer Evaluation (FMA) and modified Barthel index (MBI). For the changes in motor function of limbs and daily life ability before and after treatment, see **Table 2** and **Table 3**. The study showed that before treatment, the FMA and MBI of two groups had no significant differences (P > 0.05). In-group comparison before and after treatment, it showed that after treatment, the FMA and MBI were significantly raised in the two groups (P < 0.05), and the FMA and MBI of the treatment group were significantly higher than those of the control group (P < 0.05). After treatment, the two groups all obtained quite good therapeutic effect. However, the group treated by the combination of acupuncture with rehabilitation treatment was superior to the group treated by only rehabilitation.[15, level I]

Table 2: Changes in FMA before and after treatment

Observation item	Treatment group (n=30)		Control group (n=30)	
	Before treatment	After treatment	Before treatment	After treatment
Upper limb motor function	12.81±4.32	48.03±8.25*▲	12.76±3.85Δ	38.43±8.72*
Lower limb motor function	17.88±5.23	29.34±4.15*▲	18.17±5.43Δ	25.78±6.76*
Total motor function	30.09±6.58	75.37±10.02*▲	30.93±7.28Δ	64.21±8.83*

Note: Between-group comparison of upper, lower limb and total motor function before treatment, Δ P>0.05; in-group comparison of upper, lower limb and total motor function before and after treatment, *P<0.05; between-group comparison of upper, lower limb and total motor function after treatment, ▲ P<0.05.

Table 3: Changes in Barthel index before and after treatment

Group	*n*	Daily life ability (MBI)	
		Before treatment	After treatment
Treatment	30	27.28±5.41Δ	80.78±12.79*▲
Control	30	28.01±4.48Δ	60.08±11.92*▲

Note: Between-group comparison of MBI before treatment, Δ P>0.05; in-group comparison of MBI before and after treatment, * P<0.05; between-group comparison of MBI after treatment ▲ P<0.05.

A multi-centre RCT by Ning L et al. 2012 evaluated the therapeutic effects of acupuncture and massage for shoulder-hand syndrome in hemiplegia patients. The 120 subjects from 202 stroke patients (treated during July 2008 to July 2010) were randomly divided into an acupuncture-massage group and a rehabilitation group, with 60 cases in each. A random encoding plan was designed using SPSS software and concealed in an envelope. All patients finished the treatment and had a follow-up visit. The primary indices evaluated were pain on passive movement of the shoulder using the numeric pain rating scale (NPRS), and the number of patients with shoulder-hand syndrome at Steinbrocker stage II or III after treatment. The secondary indices were Fugl-Meyer evaluation of functional movement of the upper limb and hand using the modified ranking scale (MRS). The study indicated that there was no statistical difference in NPRS score before treatment between the two groups. However, there were statistical differences (P < 0.05) after the 6-week treatment and at the 3-month follow-up visit. After treatment, fewer patients in the acupuncture-massage group had stage II or III shoulder-hand syndrome than in the rehabilitation group; this was a significant difference (P < 0.05) that remained at the 3-month follow-up visit, indicating that acupuncture-massage therapy is superior to rehabilitation therapy in treating shoulder-hand syndrome and preventing its deterioration. There was no statistical difference (P > 0.05) in total score before treatment or at the 3-month follow-up visit between the two groups for Fugl-Meyer evaluation of upper limb. However, there was a statistical difference (P < 0.05) in total score after 6-weeks of treatment. The score for hand function before treatment differed from that after the 6-week treatment period and at the 3-month follow-up visit in both groups (P < 0.05), indicating that both therapies improved functional hand activity. There was no statistical difference (P > 0.05) in the score after 6-weeks of treatment or at the 3-month follow-up visit between the two groups, indicating that the two therapies had a similar curative effect. There was no statistical difference (P > 0.05) in MRS before treatment between the two groups. After treatment and at the 3-month follow-up visit, disability was improved in significantly more patients in the acupuncture-massage group than in the rehabilitation group (P < 0.05). The authors concluded that standardized acupuncture-massage therapy may have curative effects on shoulder-hand syndrome in hemiplegia patients.[16, level I]

5.2 Safety

There was no retrievable evidence to suggest that acupuncture for post-stroke rehabilitation is unsafe in comparison with other conventional therapies. However, there was one trial reported on the adverse events, namely a slight risk of hematoma around the acupuncture points, dizziness, and seizure. Another trial reported the death of two subjects possibly related to scalp acupuncture. Unfortunately, the cause and effect relationship with intervention was not mentioned.[12, 13, level I]

5.3 Cost/economic analysis

There was no retrievable evidence on the cost-effectiveness or a single economic analysis of acupuncture for post-stroke rehabilitation. The cost per session varies according to scope of treatment ranges between RM 60 to RM 120. However, it was provided free of charge by T&CM unit in several dedicated governmental hospitals.

5.4 Limitation

Our review has several limitations. The selection of the studies and appraisal was done by one reviewer. Although there was no restriction in language during the search, only English full text articles were included in the report. The most important limitation was the methodological quality of the included trials which had a high risk of bias. The inappropriate randomised sequence generation, lack of allocation concealment, and an inadequate level of blinding could cause selection or study quality bias. Another weakness is the poor description of patient withdrawals from the studies and the adverse events. Moreover, a cost analysis should also be considered.

6.0 CONCLUSION

The evidence on the effectiveness of acupuncture for post-stroke rehabilitation was high of level. However, the included trials in most of the systematic reviews have biases due to inappropriate randomised sequence generation, lack of allocation concealment, inadequate level of blinding, poor description of patient withdrawals from the studies and the adverse events and hence, varying the quality of the included trials. Nevertheless, findings from the systematic reviews showed that acupuncture seemed to be superior to conventional treatments or provide added value in terms of neurological function outcomes, motor recovery, activities of daily living, quality of life, and particularly the case for post-stroke spasticity and shoulder-hand syndrome in hemiplegia patients. Acupuncture treatment for post-stroke rehabilitation however, may be safe

with minimal adverse events. There was no retrievable evidence on its cost-effectiveness.

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10. Wu HM, Tang JL, Lin XP, Lau JTF, Leung PC, Woo J, Li Y. Acupuncture for stroke rehabilitation. Cochrane Database Syst Rev 2006; 3: CD004131. DOI: 10.1002/14651858.CD004131.pub2.
11. Wu P, Mills E, Moher D. Acupuncture in post-stroke rehabilitation: a systematic review and meta-analysis of randomized trials. Stroke 2010; 41: e171–e179
12. Kong JC, Lee MS, Shin BC, Song YS, Ernst E. Acupuncture for functional recovery after stroke: a systematic review of sham-controlled randomized clinical trials. CMAJ. 2010; 182: 1723–1729
13. Lee SJ, Shin BC, Lee MS, Han CH, Kim JI. Scalp acupuncture for stroke recovery: a systematic review and meta-analysis of randomized controlled trials. Eur J Int Med 2013; 5: 87–99
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15. Mao M, Chen X, Chen Y, Rao P, Liu J. Stage-oriented comprehensive acupuncture treatment plus rehabilitation training for apoplectic hemiplegia. J Tradit Chin Med. 2008; 28(2): 90-93

16. Ning L, Fengwei T, Chengwei W, Pengming Y, Xi Z, Qian W, Xiulan Q, Lu H. Therapeutic effect of acupuncture and massage for shoulder-hand syndrome in hemiplegia patients: a clinical two-center randomised controlled trial. J Tradit Chin Med. 2012; 32(3): 343-349

8.0 APPENDIX

8.1 Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-Process & Other Non-indexed Citations and Ovid MEDLINE® 1946 to present

1.	Cerebrovascular Disorders/ or "Activities of Daily Living"/ or Stroke/ or Hemiplegia/
2.	(Cerebral adj1 stroke*).tw.
3.	Stroke*.tw.
4.	(Stroke* adj1 acute).tw.
5.	(Cerebrovascular adj1 apoplexy).tw.
6.	Apoplexy.tw.
7.	Cerebrovascular accident*.tw.
8.	(Cerebrovascular accident* adj1 acute).tw.
9.	(Brain adj1 vascular accident*).tw.
10.	(Cerebrovascular adj1 stroke*).tw.
11.	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12.	(Vascular disease* adj1 intracranial).tw.
13.	(Vascular disorder* adj1 (intracranial or brain)).tw.
14.	(Cerebrovascular adj1 (occlusion or insufficiency*)).tw.
15.	Cerebrovascular disorder*.tw.
16.	12 or 13 or 14 or 15
17.	Rehabilitation.tw.
18.	(Self adj1 care*).tw.
19.	(Daily living adj2 activity*).tw.
20.	(Limitation of activity adj1 chronic).tw.
21.	17 or 18 or 19 or 20
22.	Monoplegia*.tw.
23.	Hemiplegia*.tw.
24.	Hemiplegia* transient.tw.
25.	Hemiplegia* spastic.tw.
26.	(Hemiplegia* adj1 (infantile or spastic or post ictal or crossed or flaccid)).tw.
27.	22 or 23 or 24 or 25 or 26
28.	Acupuncture Analgesia/ or Acupuncture Therapy/ or Acupuncture/ or Acupuncture Points/ or Acupuncture, Ear/
29.	Acupuncture.tw.
30.	(Acupuncture adj1 anesthesia).tw.
31.	(Acupuncture adj1 analgesia).tw.

32.	(Acupuncture* adj1 auricular).tw.
33.	(Acupuncture* adj1 ear).tw.
34.	Acupoint*.tw.
35.	(Acupuncture adj1 point*).tw.
36.	(Acupuncture adj1 therapy).tw.
37.	29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38.	27 and 37
39.	Limit 38 to English language

OTHER DATABASES	
EBM Reviews – Cochrane Central Registered of Controlled Trials	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews – Database of Abstracts of Review of Effects	
EBM Reviews – Cochrane database of systematic reviews	
EBM Reviews – Health Technology Assessment	
NHS economic evaluation database	
PubMed	Same MeSH, keywords, limits used as per MEDLINE search
INAHTA	
US FDA	

8.2 Appendix 2

HIERARCHY OF EVIDENCE FOR EFFECTIVENESS STUDIES

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Park J, Hopwood V, White AR, Ernst E. Effectiveness of acupuncture for stroke: a systematic review. J Neurol 2001; 248: 558–563.	**Systematic review** Four independent computerised literature searches (in MEDLINE, Cochrane Controlled Trials Register, Embase, and CISCOM databases) were conducted in June 1999. All RCTs that compared any form of needle insertion acupuncture to any form of non-acupuncture control intervention in the treatment of human stroke patients were included. The methodological quality of the included studies was assessed using the Jadad score.	I	The total number of subjects enrolled in the trials was 538, of whom 288 received acupuncture.	Needle insertion acupuncture	Non-acupuncture		Eventually, nine studies were included in the review. One study used assessor and subject blinding, two studies blinded the assessor, and one blinded the subjects only. Two studies used manual acupuncture, five electro-acupuncture, and two used both techniques. Standard medical and rehabilitative treatments or sham electro-acupuncture were used as control intervention. A range of outcome measures was used: the Scandinavian Stroke Scale, Chinese Stroke Scale or Recovery measure, Barthel Activities of Daily Living (ADL) index, Nottingham Health Profile (NHP), Motor function, balance, and number of days in hospital. Of the nine studies, six yielded a positive result suggesting that acupuncture is effective, and three produced a negative finding implying that acupuncture is not superior to control treatment. Only two studies obtained a Jadad score of more than 3. These methodologically best trials showed no significant effect of acupuncture.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Wu HM, Tang JL, Lin XP, Lau JTF, Leung PC, Woo J, Li Y. Acupuncture for stroke rehabilitation. Cochrane Database Syst Rev 2006; 3: CD004131. DOI: 10.1002/14651858.CD004131.pub2.	**Systematic review** Computerised literature searches were conducted including MEDLINE, Cochrane Trials Register, Embase, CINAHL, AMED, Chinese Stroke Trials Register, Chinese Acupuncture Trials Register, Chinese Biological Medicine Database, National Center for Complementary and Alternative Medicine Register, and National Institute of Health Clinical Trials Database. They hand searched four Chinese journals and checked reference lists of all papers identified for further trials. RCTs comparing acupuncture with at least one control group that used placebo, sham treatment or conventional treatment were included. Two review authors independently selected trials for inclusion, assessed quality, extracted and cross-checked the data.	I	Trials involving patients of any age or sex with ischemic or haemorrhagic stroke in the subacute (one to three months since onset) or chronic phases (over three months since onset)	Acupuncture therapy which involved needling	Placebo acupuncture, sham acupuncture, or other conventional treatment		Fifty potentially eligible trials were retrieved. Of these, five trials including a total of 368 patients met inclusion criteria. Methodological quality was considered inadequate in all trials. No trial described the method of randomisation, and allocation concealment was unclear in all included trials. Only one trial reported that participants were blinded but did not describe the method in detail. There was no statement on dropouts or withdrawals in any of the included trials. No data on death, dependency, institutional care, change of neurological deficit score, quality of life or adverse events were available. Although the overall estimate from four trials suggested the odds of improvement in global neurological deficit was higher in the acupuncture group compared with the control group [odds ratio (OR) 6.55, 95% confidence interval (CI) 1.89 to 22.76], this estimate may not be reliable since there was substantial heterogeneity (I^2= 68%). One trial showed no significant improvement of motor function between the real acupuncture group and the sham acupuncture group (OR 9.00, 95% CI 0.40 to 203.30), but the confidence interval was wide and included clinically significant effects in both directions.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Wu P, Mills E, Moher D, Seely D: Acupuncture in poststroke rehabilitation: a systematic review and meta-analysis of randomized trials. Stroke 2010; 41: e171–e179.	**Systematic review with meta-analysis** They searched the following English electronic databases: MEDLINE, AMED, Alt Health Watch, CINAHL, Nursing and Allied Health Collection: Basic, and Cochrane Database of Systematic Reviews from inception to September 2009. In addition, they searched the Chinese database CNKI, CBM, and Wan Fang independently. No language of publication restrictions was placed on the searches. Eligible studies included RCTs that evaluated the clinical efficacy of acupuncture in adult patients with disability after stroke. They extracted data on trial quality, protocol, and outcomes assessed. A summary OR was calculated based on pooled dichotomous results. The I^2 was used to infer heterogeneity and they also conducted metaregression to determine if specific covariates explained heterogeneity. Funnel plot was displayed to address the potential for publication bias.	I	Adult patients (> 18 years) with disability due either to ischemic or hemorrhagic stroke. The 56 RCTs included 5,650 patients; 3,156 in the treatment groups and 2,494 in the control groups.	Active acupuncture	Sham acupuncture or no acupuncture treatment		**Characteristics of included studies** Thirty-five articles written in Chinese and 21 articles written in English were included. The trials were relatively small (median n=86; range, 16 to 241) and 99 of 939 patients reported to have dropped out over 11 studies combined. Four studies provided no information on this issue and 100% completed treatment in the remaining 41 studies. Thirty-nine of the 56 studies provided detailed information based on the STRICTA guidelines. The trials used various outcome measures included motor impairment scales, generalized stroke scales, and disability assessments. Side effects were detailed in a few of the studies but were generally poorly reported. **Risk of bias of the trials** In general, randomization and allocation concealment were poorly reported. Only 25% (14/56) of the studies gave detailed accounts of how patients were randomized. A total of 12.5% of the studies (7/56) adequately reported allocation concealment. Patients were blinded in 11% (6/56) of the in which sham acupuncture was used as a control. Assessor blinding was reported in a total of 28.6% (16/56) studies. **Efficacy of acupuncture in poststroke rehabilitation** Positive results were reported in 45 of the 56 studies. Six studies reported a positive benefit only in a subgroup analysis. No significant differences between acupuncture intervention and control were reported in 5 studies. In 38 trials, data were available for meta-analysis and meta-regression, yielding an OR in favour of acupuncture compared with controls (OR=4.33, 95% CI: 3.09 to 6.08; I^2=72.4%). Randomization, modes of delivery, method of control, study source country, and reporting of randomization may explain some of the heterogeneity observed between the studies.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Kong JC, Lee MS, Shin BC, Song YS, Ernst E. Acupuncture for functional recovery after stroke: a systematic review of sham-controlled randomized clinical trials. CMAJ. 2010; 182: 1723–1729.	**Systematic review with meta-analysis** Following databases were searched: MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycINFO, the Cochrane Library (2009; issue 4), and Asian journals and 12 major Korean traditional medicine journals. RCTs with no language restrictions that compared the effects of acupuncture (with or without electrical stimulation) with sham acupuncture were included. They assessed the methodological quality of the trials using the Cochrane risk-of-bias criteria and the PEDro (Physiotherapy Evidence Database) scale. Outcome measures: neurologic deficit, activities of daily living (i.e., Barthel Index or Fugl–Meyer Assessment), motor recovery, quality of life, and adverse events.	I	RCTs involving patients of any age or sex with ischemic or hemorrhagic stroke in the acute, subacute or chronic stage.	Needle acupuncture (with or without electrical stimulation)	Sham acupuncture (acupuncture with or without needle penetration at the acupuncture points or non - acupuncture points) or subliminal acupuncture (electrostimulation using electrodes attached to the skin)		**Study description** Ten of 664 potentially relevant studies involving 711 participants met the inclusion criteria. Seven trials included patients in the acute or subacute stage of stroke, and three included patients in the chronic stage. **Study quality** Five trials used blinding of participants and assessors, three used blinding of participants only, and two used blinding of assessors only. Three trials reported details about allocation concealment. **Outcome measures** Four trials tested the effects of acupuncture on neurologic deficits using the National Institutes of Health Stroke Scale, the European Stroke Scale or the Scandinavian Stroke Scale. One of the four studies showed positive therapeutic effects. Seven trials tested the effects of acupuncture on activities of daily living according to the Barthel Index, the modified Barthel Index or the Sunaas Index of Activities of Daily Living. Two of these studies (both from China) showed favourable effects on activities of daily living. Of the five trials that assessed the effects of acupuncture treatment on quality of life, none showed favourable effects. A meta-analysis of the five studies that assessed functionality which involved patients in the acute and subacute stages of stroke did not show a significant difference in favour of acupuncture, with high heterogeneity (n=368; standard mean difference 0.47, 95% confidence interval [CI]–0.02 to 0.96; I^2=81%). A post-hoc sensitivity analysis of three trials with low risk of bias did not show beneficial effects of acupuncture on activities of daily living at the end of the intervention period (n=244; standard mean difference 0.07, 95% CI–0.18 to 0.32; I^2=0%) or after follow-up (n=244; standard mean difference 0.10, 95% CI –0.15 to 0.35; I^2=0%). For the chronic stage after stroke, three trials tested effects of acupuncture on function according to the Modified Ashworth Scale; all failed to show favourable effects.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Lee SJ, Shin BC, Lee MS, Han CH, Kim JI: Scalp acupuncture for stroke recovery: a systematic review and meta-analysis of randomized controlled trials. Eur J Int Med 2013; 5: 87–99.	**Systematic review with meta-analysis** Two independent reviewers searched the following 16 electronic databases from their inception through June 2012: PubMed, Medline, The Cochrane Library 2012 (Issue 6), CINAHL, China Academic Journal, Wanfang Med Online, 9 Korean Medical Databases and the Japanese Medical Database. This review included both parallel and cross-over RCTs that studied the effects of scalp acupuncture (SA) (with or without electrical stimulation) on stroke recovery. No restriction was imposed on language or publication form. Methodological quality was assessed using the Cochrane risk of bias tool.	I	Human patients diagnosed with stroke by neuroimaging methods or according to the World Health Organization (WHO) guidelines were included regardless of age, gender, race or the stage of stroke.	Scalp acupuncture as a sole or adjunct treatment with any relevant controls for stroke	No treatment, sham (or placebo) (scalp) acupuncture or relevant conventional therapies (CTs)		**Study description** They found 1,811 potentially relevant studies, of which 21 publications (2,172 stroke patients) fit the criteria for inclusion. Of those 21 publications, 14 trials studied 1,634 acute or subacute stroke patients, and 3 RCTs studied 223 chronic stroke patients. The remaining 4 trials included 315 mixed-stage stroke patients. **Risk of bias across the studies** The quality of the included RCTs was generally low. Ten trials used proper random sequence generation methods. None of the included trials conducted allocation concealment. Patient blinding was reported in only 2 RCTs. Furthermore, 7 RCTs did not clearly describe any blinding methods. **Outcomes** Among the 14 trials, 8 used the total efficacy rate as the main outcome, and their meta-analysis showed a favourable effect on outcomes of SA plus conventional care compared to conventional care alone (medication p =0.007, and rehabilitation p=0.02). Similar favourable results were shown in the outcomes of activities of daily living (Barthel index; medication $p < 0.0001$, and rehabilitation $p < 0.00001$) and neurological function outcomes (medication $p < 0.00001$), but not in the motor function (Fugl–Meyer assessment, p=0.30). No significant differences were shown in total efficacy rate, Barthel index, or Fugl-Meyer assessment values for sole SA compared with conventional care alone. For the chronic and mixed stages of stroke, no meaningful results were obtained. Because of the poor methodological quality of all included trials, a sensitivity analysis by study quality could not be performed.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
6. Sung ML, Junghee Y, Euiju L, Hyun JK, Seungwon S, Gajin H, Hyeong SA. Acupuncture for spasticity after stroke: A systematic review and meta-analysis of randomized controlled trials. Evid Based Complement Alternat Med. 2014; ID870398	**Systematic review with meta-analysis** They searched publications in Medline, EMBASE, and the Cochrane Library in English, 19 accredited journals in Korean, and the China Integrated Knowledge Resources Database in Chinese through to July 30, 2013. RCTs with no language restrictions that compared the effects of acupuncture or electro-acupuncture with usual care or placebo acupuncture were included. The two investigators assessed the risk of bias and statistical analyses were performed. Assessments were performed primarily with the Modified Ashworth Scale (MAS).	I	Poststroke patients with spasticity	Acupuncture or electro-acupuncture	Placebo acupuncture or other conventional therapy		**General characteristics of the studies** 187 publications were identified, of which 5 RCTs were finally included by the eligibility criteria. Three RCTs in English, 1 in Korean, and 1 in Chinese. **Assessment of risk of bias (ROB)** Many of the reviewed studies were of low quality and had methodological shortcomings, such as an inadequate level of blinding. **Meta-analysis of the results** The pooled data showed a weighted mean difference of 0.72 and 95% confidence intervals of 0.29 to 1.14 on the MAS, indicating that acupuncture or electro-acupuncture had a significant effect on decreasing poststroke spasticity ($P < 0.001$). In the subgroup analysis examining the types of acupuncture, electro-acupuncture therapy significantly decreased spasticity after stroke (weighted mean difference of 0.76, 95% CI [0.25, 1.27], P=0.004), while acupuncture therapy showed slightly, but not significantly, decreased spasticity (weighted mean difference of 0.58, 95% CI [−0.69, 1.85], P=0.37). The subgroup analysis based on the regions of spasticity revealed that acupuncture or electro-acupuncture significantly reduced spasticity of wrists (weighted mean difference of 0.68, 95% CI [0.03, 1.33], P=0.04), knees (weighted mean difference of 0.70, 95% CI [0.51, 0.89], $P < 0.001$), or elbows (weighted mean difference of 0.74, 95% CI [0.55, 0.94], $P < 0.001$). There was some alleviation of spasticity of ankle region, but this was not statistically significant (weighted mean difference of 0.58, 95% CI [−0.69, 1.85], P=0.37).	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
7. Mao M, Chen X, Chen Y, Rao P, Liu J. Stage-oriented comprehensive acupuncture treatment plus rehabilitation training for apoplectic hemiplegia. J Tradit Chin Med. 2008; 28(2): 90-93	**Randomised control trial** The 60 cases of acute apoplectic hemiplegia were divided randomly into the treatment and control groups with 30 in each. The evaluation was done on the motor function and daily life ability for both groups respectively with simplified Fugl-Meyer Evaluation (FMA) and modified Barthel index (MBI). SPSS 10.0 statistical software was applied for processing all the data in research.	I	Patients who were diagnosed as having early-stage hemorrhagic and ischemic apoplectic hemiplegia	Stage-oriented comprehensive acupuncture treatment plus rehabilitation	Rehabilitation treatment	Three months after treatment	Before treatment, the FMA and MBI of two groups had no significant differences (P>0.05), being comparable. In-group comparison before and after treatment showed that after treatment, the FMA and MBI were significantly raised in the two groups (P<0.05) After treatment, the FMA and MBI of the treatment group were significantly higher than those of the control group (P<0.05). After treatment, the two groups all obtained quite good therapeutic effect. However, the group treated by the combination of acupuncture with rehabilitation treatment was superior to the group treated by only rehabilitation.	

Evidence Table : Effectiveness
Question : What is the effectiveness of acupuncture for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
8. Ning L, Fengwei T, Chengwei W, Pengming Y, Xi Z, Qian W, Xiulan Q, Lu H. Therapeutic effect of acupuncture and massage for shoulder-hand syndrome in hemiplegia patients: a clinical two-center randomized controlled trial. J Tradit Chin Med. 2012; 32(3): 343-349	**Randomised controlled trial** The 120 subjects from 202 stroke patients (treated during July 2008 to July 2010) were randomly divided into an acupuncture-massage group and a rehabilitation group, with 60 cases in each. A random encoding plan was designed using SPSS software and concealed in an envelope. All patients finished the treatment and had a follow-up visit. The primary indices evaluated were pain on passive movement of the shoulder using the numeric pain rating scale (NPRS), and the number of patients with shoulder-hand syndrome at Steinbrocker stage II or III after treatment. The secondary indices were Fugl-Meyer evaluation of functional movement of the upper limb and hand using the modified ranking scale (MRS).	I	One hundred and twenty hemiplegia patients (age 18-75 years) with stage I shoulder-hand syndrome	Standardized electric acupuncture and massage	Rehabilitation therapy	At the end of the 6-weeks treatment period and at the 12th-week follow-up visit	**NPRS score** There was no statistical difference in NPRS score before treatment between the two groups. However, there were statistical differences (P<0.05) after the 6-week treatment and at the 3-month follow-up visit. **Stage of shoulder-hand syndrome** After treatment, fewer patients in the acupuncture-massage group had stage II or III shoulder-hand syndrome than in the rehabilitation group; this was a significant difference (P<0.05) that remained (P<0.05) at the 3-month follow-up visit, indicating that acupuncture-massage therapy is superior to rehabilitation therapy in treating shoulder-hand syndrome and preventing its deterioration. **Fugl-Meyer evaluation of upper limb** There was no statistical difference (P>0.05) in total score before treatment or at the3-month follow-up visit between the two groups. However, there was a statistical difference (P<0.05) in total score after 6-weeks of treatment. **Fugl-Meyer evaluation of hand** The score for hand function before treatment differed from that after the 6-week treatment period and at the 3-month follow-up visit in both groups (P<0.05), indicating that both therapies improved functional hand activity. There was no statistical difference (P>0.05) in the score after 6-weeks of treatment or at the 3-month follow-up visit between the two groups, indicating that the two therapies had a similar curative effect. **MRS** There was no statistical difference (P>0.05) in MRS before treatment between the two groups. After treatment and at the 3-month follow-up visit, disability was improved in significantly more patients in the acupuncture-massage group than in the rehabilitation group (P<0.05).	

Evidence Table : Safety
Question : Is the acupuncture safe for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Kong JC, Lee MS, Shin BC, Song YS, Ernst E. Acupuncture for functional recovery after stroke: a systematic review of sham-controlled randomized clinical trials. CMAJ. 2010; 182: 1723–1729.	**Systematic review with meta-analysis** Following databases were searched: MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycINFO, the Cochrane Library (2009; issue 4), and Asian journals and 12 major Korean traditional medicine journals. RCTs with no language restrictions that compared the effects of acupuncture (with or without electrical stimulation) with sham acupuncture were included. They assessed the methodological quality of the trials using the Cochrane risk-of-bias criteria and the PEDro (Physiotherapy Evidence Database) scale. Outcome measures: neurologic deficit, activities of daily living (i.e., Barthel Index or Fugl–Meyer Assessment), motor recovery, quality of life, and adverse events.	I	RCTs involving patients of any age or sex with ischemic or hemorrhagic stroke in the acute, subacute or chronic stage.	Needle acupuncture (with or without electrical stimulation)	Sham acupuncture (acupuncture with or without needle penetration at the acupuncture points or non - acupuncture points) or subliminal acupuncture (electrostimulation using electrodes attached to the skin)		Four trials reported on the occurrence of adverse events: one reported a case of seizure in the acupuncture group, another noted five cases of hematoma around the acupuncture points, a third trial recorded two cases of dizziness (without group information), and the fourth trial reported no adverse events.	

Evidence Table : Safety
Question : Is the acupuncture safe for post-stroke rehabilitation?

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Lee SJ, Shin BC, Lee MS, Han CH, Kim JI: Scalp acupuncture for stroke recovery: a systematic review and meta-analysis of randomized controlled trials. Eur J Int Med 2013; 5: 87–99.	**Systematic review with meta-analysis** Two independent reviewers searched the following 16 electronic databases from their inception through June 2012: PubMed, Medline, The Cochrane Library 2012 (Issue 6), CINAHL, China Academic Journal, Wanfang Med Online, 9 Korean Medical Databases and the Japanese Medical Database. This review included both parallel and cross-over RCTs that studied the effects of scalp acupuncture (SA) (with or without electrical stimulation) on stroke recovery. No restriction was imposed on language or publication form. Methodological quality was assessed using the Cochrane risk of bias tool.	I	Human patients diagnosed with stroke by neuroimaging methods or according to the World Health Organization (WHO) guidelines were included regardless of age, gender, race or the stage of stroke.	Scalp acupuncture as a sole or adjunct treatment with any relevant controls for stroke	No treatment, sham (or placebo) (scalp) acupuncture or relevant conventional therapies (CTs)		Only 3 of the 21 RCTs [42,43,49] described adverse events possibly related to SA. Two of them reported no adverse events, and 1 reported the death of 2 subjects. The cause and-effect relationship with intervention was not mentioned.	