Migraine

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Diener et al, 2006[221] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** 149 Outpatient departments **Duration of follow-up:** 6 months	**Patient group**: Adults with migraine **Inclusion criteria:** Aged 18—65. Between two and six migraine attacks in 4 weeks; first migraine attack before the age of 50; migraine diagnosis at least 26 weeks before study entry; duration of migraine attacks 4-72 hr without acute medication or at least 2hr with acute medication. Two migraine characteristics were to be met and at least one of the following: nausea, vomiting, photophobia or phonophobia. **Exclusion criteria:** Severe migraine attacks with inability to go to work on more than 4 days a month; other neurological disease; secondary headache; neuralgia of the face or head; more than 6 days of non-migrainous headache per month; experience with acupuncture for migraine; any body needle acupuncture in the past 12 months; previous unsuccessful treatments with beta blockers; drug abuse; pregnancy; lactation; insufficient contraception; intake of antipsychotic or antidepressant drugs. Patients were also excluded if they had participated in another clinical trial, taken analgesics on more than 3 days a month for other chronic pain, used prophylactic	**Group 1 Acupuncture** Chinese acupuncture points consisted of obligatory points and additional points individually chosen by the physicians on the basis of traditional Chinese medicine diagnosis for syndromes (including tongue diagnosis), acupuncture channels related to the headache area, and Ah Shi points (locus dolendi points). Needles were inserted 2-20mm in depth and manual stimulation of the needle was applied to achieve 'De Qi' based on subjective reporting of the patient. **Group 2 Sham** Acupuncture done on areas of the skin in which no traditional Chinese medicine acupuncture points are known. Up to 6 needles were applied superficially on either side of the upper arm, on both thighs and below both scapulae (depth of needle insertion max 3mm), and no manual stimulation was done. The head has a high density of acupuncture points and was excluded from sham acupuncture sessions. **Both groups:** Consisted of 10 sessions of 30 minutes	**Change in patient-reported migraine days** (change from baseline, mean (SD))	**At 13 weeks** **Group1:** -2.2 (3.1) **Group 2:** -1.9 (3.6)	**Funding:** Various public health insuring bodies **Limitations:** Single blind (patients and assessors blind). Acupuncture group treated with significantly more needless than sham (15.4 (4.6) vs 13.8 (4.3) p<0.0001) **Additional outcomes:** Pain-related impairment and pain days according to von Korff; patient global assessment of therapy effectiveness; quality of acupuncture therapy; maintenance of blinding. **Notes:** ITT analysis used last observation carried forward for missing data. Outcomes recorded in diaries. 44% of patients
			Change in patient-reported migraine days (change from baseline, mean (SD))	**At 26 weeks** **Group1:** -2.3 (3.6) **Group 2:** -1.5 (3.8) **95% CI:** Group1: 1.9;2.7, Group2 1.1;2.0 **p value:** 0.031	
			Patient-reported migraine intensity (Pain intensity on Von Korff scale (0-10), baseline and final values, mean (SD))	**At 13 weeks** **Group1: Baseline 73.7 (13.3), Final 63.5 (19.1)** **Group 2:** Baseline73.8 (13.3), Final 62.6 (18.9) **p value**: 0.393	
			Patient-reported migraine intensity (Pain intensity on Von Korff scale (0-10), change from baseline, mean (SD)). Scale NR.	**At 26 weeks** **Group1: Final 57.7 (20.4)** **Group 2:** 60.9 (20.4) **95% CI:** Group1: 1.9;2.7, Group2 1.1;2.0 **p value:** 0.045	
			Responder rate (50% reduction in	**At 13 weeks** **Group1: 128/290**	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	medication for migraine in past 6 months, were receiving cortisone treatment, had epilepsy or had a psychiatric disease. **All patients** N: 960 randomised, 835 treated **Group 1 – Acupuncture** **N:** 313 randomised, 305 received treatment, 290 analysed **Age (mean):** 37.1 (10.5) **Drop outs:** 8 pre-treatment, 15 after **Migraine attacks/month:** 3.8 (3.0) **Migraine days:** 6.0 (3.2) **With/without aura:** 52/48% **Disease duration, months:** 201.6 (150.9) **Days with other headache:** 1.5 (2.9) **Using medication for other pain:** 21 (22%)	duration, administered over 6 weeks preferably at a rate of two sessions per week. Only body needle acupuncture without electrical stimulation or moxibustion was allowed. The same number and type of needles (sterile, single-use acupuncture needles, coated 0.25-0.30mm thick, 25-40mm long) were used in both treatment groups. The investigators were instructed to provide the same level of care and attention to both groups. Total number of needles was restricted to a maximum of 25 and a minimum of ten per treatment. Both verum and sham points had to be selected from a prescribed list and needling was bilateral. During treatment, communication with the patient was restricted to a minimum of necessary explanations to avoid unblinding of the patient. For the purpose of this study acupuncture points were established on basis of international literature and consultation with experts. To better approximate clinical practice, all patients could receive 15 instead of 10 interventions 9to per week) if their treatment was graded as only partly successful in the telephone interview at the end of the treatment phase. **Group 3 Standard treatment**	migraine days, n (%))	**(46%)** **Group 2:** 128/317 (42%) **At 26 weeks** **Group1:** 133 (47%) **Group 2:** 121 (39%)	correctly guessed whether they were receiving verum or sham acupuncture (119 (42%) verum, 81 (26%) sham). Only 28% guessed wrong.
	Pervious acupuncture >12mo pre screening (not for migraine): 41 (14%) **Group 2 - Sham** **N:** 339 randomised, 328 received treatment, 317 analysed **Age (mean):** 38.3 (10.4) **Migraine attacks/month:** 3.8 (3.0) **Migraine days:** 5.8 (3.2) **With/without aura:** 48/52% **Disease duration, months:** 199.5 (131.7)		**Use of acute pharmacological treatment** (baseline and final n of people using acute medication (%)	At 13 weeks Group1: Baseline 270 (93%) Final 254 (89%) Group 2: Baseline 292 (92%) Final 272 (87%)	
			Use of acute pharmacological treatment (baseline and final n of people using (%)	**At 26 weeks** **Group1:** Final 254 (88%) **Group 2:** Final 272 (86%)	
			Functional health status and health-related quality of life (SF-12 physical health mean (SD) baseline and final values)	At 13 weeks Group1: Baseline 43.2 (8.4) Final 47.6 (7.3) Group 2: Baseline 42.7 (8.8) Final 46.0 (8.2) p value: 0.029	
			Functional health status and health-related quality of life (SF-12 mental health	Group1: Baseline 48.5 (9.5) Final 51.5 (8.4) **Group 2**: Baseline	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	Days with other headache: 2.1 (3.9) **Using medication for other pain:** 32 (37%) **Pervious acupuncture >12mo pre screening (not for migraine):** 42 (13%) **Drop outs:** 11 pre-treatment, 11 after **Group3 – Standard care** **N: 308 randomised, 202 received treatment, 187 analysed**	Not reported here including use of beta-blockers, flunarazine or valproic acid).	mean (SD))	48.1 (9.9) Final 50.9 (8.8)	
			Functional health status and health-related quality of life (SF-12 physical health mean (SD) baseline and final values)	**At 26 weeks** **Group1: Final 47.3 (8.2)** **Group 2:** Final 46.3 (8.7)	
			Functional health status and health-related quality of life (SF-12 mental health mean (SD))	**At 26 weeks** **Group1: Final 51.4 (9.0)** **Group 2:** Final 51.0 (9.4)	

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Facco et al, 2008[269] **Study design:** RCT **Comparison:** Acupuncture vs ritualised sham vs standard sham **Setting:** NR **Duration of follow-up:** 6 months	**Patient group:** Adults with migraine without aura (with or without tension-type symptoms) **Inclusion criteria:** Diagnosis of migraine without aura according to ICHD, with or without tension-type symptoms; frequency of migraine attacks 3-8 per month; previously received at least one prophylactic treatment for migraine with no improvement. **Exclusion criteria:** Onset of headache or acupuncture treatment less than 1-year before; headache caused by other diseases **All patients** **N:** 160 enrolled, 127 completed **Drop outs:** 33	**Group 1 – True acupuncture** Patients clinically evaluated according the traditional Chinese medicine (TCM) syndrome definition. Each type of syndrome was treated with a specific acupoint selection according to TCM as suggested by Liu Gongwan (personal communication) the acupoints were defined according to the Whorld Health Orgainisation (WHO) standard acupuncture nomenclature. Twice a week, all patients were submitted to 2 courses of 10 acupuncture applications each, with a 1-week rest between the 2 courses. Acupuncture was performed with single-use stainless steel filiform needles, 25 or 40mm long, diameter 0.30mm. After the needle insertion and arrival of Qi, the required method of treatment was applied to each acupoint (reducing method consisted of 1 minute stimulation of the needle obtained with a large rotation at a rate of about 3 rotations/second. The reinforcing method was performed with a small rotation for 1 minute at a rate of about one every 2 seconds) Stimulation was repeated 3 times at intervals of 5 minutes. The session lasted 30 minutes. **Group 2 – Ritualised mock acupuncture**	**Headache specific QoL** (MIDAS Index, Baseline and final vales, Mean±SD)	**At 3 months** **Group1 (n=32): Baseline 22.2±6.0, Final 2.1±1.5** **p value:** <0.0001 **Group 2** (n=30): Baseline 21.1±6.3, Final 5.0±1.5 **p value:** <0.0001 **Group 3** (n=31): Baseline 22.0±6.3, Final 7.5±3.3 **p value:** <0.0001 **95% CI:** NR	**Funding:** NR **Limitations:** Single blind (patients and assessors) Allocation concealment unclear Population includes those with and without tension headache Rizatriptan use at baseline not reported **Additional outcomes:** None **Notes:** Randomisation done after stratifying for sex (using random number generator in excel) Per protocol analysis
			Headache specific QoL (MIDAS Index, Baseline and final vales, Mean±SD)	**At 6 months** **Group1** (n=32): Final 2.2±1.1 **p value:** <0.0001 **Group 2** (n=30): Final 8.0±1.5 **p value:** <0.0001 **Group 3** (n=31): Final 8.2±3.2 **p value:** <0.0001 **95% CI:** NR	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 1 – Acupuncture **N:** 32 **Age (mean):** 35.2 ± 6.1 (25-48) **M/F:** 14/18 **Drop outs:** 8 **Group 2 – Ritualised mock acupuncture** **N:** 30 **Age (mean):** 39.4 ± 6.4 (25-50) **M/F:** 14/16 **Drop outs:** 10 **Group 3 – Standard mock acupuncture** **N:** 31 **Age (mean):** 35.4 ± 6.3 (25-48) **M/F:** 15/16 **Drop outs:** 9	Acupuncture apparently the same as in group 1 but the needles were not inserted. A small cylinder of foam (height and diameter=1cm) was applied to the skin by means of a double-adhesive plaster n each acupoint; needles with blunted tips were inserted into the cylinder, touching but not penetrating the skin. This allowed the patient to feel a superficial, light pricking-like sensation, thus stimulating the needle insertion. A slight pressure was applied on the needle handle 3 times at 3 second intervals in order to simulate the arrival of "Qi". The reducing or reinforcing methods were also simulated by rotating the needles within the foam cylinder. **Group 3 – Standard mock acupuncture** The Western approach was used for diagnosis and the standard acupoint selection used (Touwei (ST8), Xuanlu (GB5), Fengchi (GB20), Dahui (GV14), Lieque (LU7)) with the same methods of insertion used in group RMA. All patients allowed to take Rizatriptan to treat attacks during prophylactic treatment with acupuncture / sham. Rizatriptan wafer administered at 10mg, a second dose was allowed after 2 hours if pain persisted.	**Use of acute pharmacological treatment** (Rizatriptan intake during treatment, no. of tablets Mean±SD)	**Group1:** 3 mo:10.0±5.0 6mo 4.2±1.5 **P value:** <0.0001 **Group 2:** 3 mo: 14.4±5.1 6mo: 17±5.0 **P value:** NS **Group 3:** 3 mo: 17.2±5.4 6 mo: 16.0±5.0 **P value:** NS **95% CI:** NR	reported only

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval, TCM=traditional Chinese medicine, RMA=ritualised mock acupuncture, ICHD=International classification of headache disorders

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Hesse et al, 1994[374] **Study design:** RCT **Comparison:** Acupuncture vs beta-blocker **Setting:** NR **Duration of follow-up:** 17 weeks	**Patient group:** Adults with migraine with or without aura **Inclusion criteria:** Aged 21-70 with a history of migraine for at least 2 years; 2-6 attacks monthly; fulfilling criteria for migraine with or without aura according to ICHD; not taking prophylactic drugs and capable of distinguishing tension-type headache from migraine pain. **Exclusion criteria:** Patients suffering from other chronic pain syndromes or with contraindication for beta-blocking agents. Previous experience with acupuncture or metoprolol, pregnancy, drug abuse or disablement pension. **All patients** **N:** 85 randomised, 77 ITT **Drop outs:** 8 (1 regretted consent at 1st visit, 4 refused during treatment (2 per group), 1 intercurrent disease, 1 pregnancy, 1 error in allocation) **Group 1 – Acupuncture + placebo** **N:** 38 **Age (mean):** 42.9 (26-66) **M/F:** 5/33 (13/87%)	**Group 1 Acupuncture + placebo** At each visit patients were dry needled for a few seconds using the sharp end of the needle. The number of trigger points per treatment, interval between treatments and total number of treatments were determined individually by the therapist according to patient's clinical response to the needling. **Group 2 Metoprolol + sham acupuncture** At each visit patients were touched superficially with the blunt end of the needle. The number of trigger points per treatment, interval between treatments and total number of treatments were chosen at random, but within the range of group A (i.e. 4-6 needlings per treatment, 1-3 weeks between treatments and 6-8 treatments during the study period). Plus metoprolol 100mg/day. After 17 weeks, it was gradually withdrawn over a period of 10 days. **Both groups:** 17 weeks of treatment preceded by a 4 week run-in period during which only symptomatic medication was allowed. At each visit patients had their most tender trigger points in musculus trapezius, m.rhomboideus and m.semi-spinalis capitis chosen for treatment.	**Change in patient-reported migraine frequency** (median difference in migraine frequency between groups)	**Group1 vs Group 2:** 0.7 **95% CI:** -1.6;2.7 **p value:** >0.20	**Funding:** Danish Health Foundation and Danish Medical Research Council **Limitations:** Single blind (patients and assessors). Randomisation and allocation concealment unclear. Selective reporting of outcomes. Baseline and final values not reported. Drop outs not reported per group. **Additional outcomes:** Duration of migraine attacks. Occurrence of tension type headache and consumption of analgesics both stated as recorded, but results not reported. **Notes:** ITT analysis usually based upon last observation carried forward (not stated when this was not the case). Outcomes recorded in a dairy card. * Global rating scale, 1=mild,
		Change in patient-reported intensity (migraine severity median difference between groups) Based on global rating*	**Group1 vs Group 2:** 0.3 **95% CI:** 0.1;0.5 **p value:** <0.05	
		Incidence of serious adverse events (%)	**Group1:** 0 **Group 2**: 1 (severe abdominal pain, withdrew from trial)	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	With/without aura: 6/32 (16/84%) **Duration of migraine (yrs):** 20.3 (2-40) **Tension type headache:** 36 (95%) **Drop outs:** NR **Group 2 – Metoprolol + sham** **N:** 39 **Age (mean):** 46.5 (25-70) **M/F:** 7/32 (18/82%) **With/without aura:** 8/31 (21/79%) **Duration of migraine (yrs):** 26.5 (2-55) **Tension type headache:** 36 (95%) **Drop outs:** NR	Patients were permitted to continue symptomatic medication, but any form of physical therapy was avoided.			2=moderate, 3=severe

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval, ICHD=International Classification of Headache Disorders

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Li et al, 2012[494] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** Outpatients (multicentre – 9 hospitals, China) **Duration of follow-up:** 16 weeks (acupuncture given for 4 weeks)	**Patient group:** Adults with migraine with or without aura **Inclusion criteria:** ICHD criteria for migraine; experienced acute migraine attacks for more than one year with two or more attacks per month during the previous three months and during the baseline period; aged 18-65 years; onset of migraine before age 50; completed a baseline headache diary' did not take any prophylactic migraine medication during the previous month; willing to complete 20 acupuncture treatments during a four-week period (weeks 1-4); and able to provide written informed consent. **Exclusion criteria:** Had headache due to organic disorders (e.g. Subarachnoid haemorrhage, cerebral haemorrhage, cerebral embolism, cerebral thrombosis, vascular malformation, arthritis, hypertension, arteriosclerosis), psychosis, pregnancy or lactation, allergies, bleeding disorders or serious diseases of the heart, liver, kidney or other organs. **All patients** **N:** 480 **Drop outs:** 4 pre treatment, 37 during treatment period **Age:** 36.9 (12.3)	**Group 1 - Acupuncture** The treatments, which included electro-stimulation, were provided by specialised acupuncturists who had at least five years' training and give years; experience using a standardised protocol. The acupuncture points were selected according to a systematic review of ancient and modern literature, consensus meetings with experts and experience from a previous study. The Shaoyang-specific and sham acupuncture points chosen were used In a previous study of acute migraine Attacks. The three acupuncture groups were: Shaoyang-specific (SS); Shaoyang-nonspecific (SN); and Yangming-specific (Y). **Group 2 sham acupuncture**	**Change in patient-reported migraine days** (baseline and final vales) Mean(95% CI) ±SD unless otherwise stated. Data reported in weeks 13-16 (wks 1-4 acupuncture treatment)	**Acupuncture:** **SS:** Baseline=6.3 (5.4-7.2), Final= 2.2 (1.7-2.7) p=0.003 **SN:** Baseline=5.6 (5-6.2), Final= 2.1 (1.6-2.6) p<0.001 **Y:** Baseline=6.1 (5.3-7) Final= 2.4 (1.9-2.9) p=0.011 **All*** Baseline=6±4.4, Final= 2.23±2.76 **Sham:** Baseline=5.5 (4.8-6.2) Final= 3.3 (2.8-3.8)	**Funding:** National Basic Research Programme of China (no role in design, data collection / analysis or manuscript) **Limitations:** Person administering treatment not blinded to group (however all other participants including outcome assessor were). SDs not given (calculated from 95% CIs by NCGC) **Additional outcomes:** Pain intensity on 0-10 VAS Patients documented pain medication taken and side effects in their diaries, but results not given. **Notes:** * Pooled values for all 3 acupuncture groups calculated by NCGC. 90% power (5% significance, 2 sided) to detect a difference of 1.6
			Change in patient-reported migraine frequency (no. migraines separated by pain free intervals of ≥48 hours) Baseline & final values	**Acupuncture:** **SS:** Baseline= 4 (3.6-4.3) Final= 1.6 (1.3-1.9) p>0.001 **SN:** Baseline=4 (3.7-4.3) Final= 1.7 (1.4-2) P=0.002 **Y:** Baseline= 4 (3.7-4.4) Final= 1.9 (1.6-2.2) P=0.024 **All*** Baseline= 4±1.84 Final= 1.73±1.66 **Sham:** Baseline= 3.9 (3.6-4.2) Final= 2.4 (2.1-2.7)	
			Change in patient-reported migraine	**Acupuncture:** **SS:** Baseline= 2.0 (1.0-2.1)	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 1 – Acupuncture Original study had 3 acupuncture groups NB these are pooled for our analysis. **N:** 358 **Shaoyang-specific** **N:** 121 randomised, 108 assessed **Dropouts:** 13 (7 reason unclear, 3 unsatisfied, 3 other reason) **Age (mean):** 37.1 (11.7) **M/F:** 21/100 **With/without aura:** 18/103 **Duration of migraine (months):** 119.8 (115.3) **Previous use of acupuncture (n):** 5 **Use of acute pain medication (n):** 35 **Shaoyang-non specific** **N:** 119 randomised, 110 assessed **Dropouts:** 9 (5 reason unclear, 4 unsatisfied) **Age (mean):** 36.2 (12.4) **M/F:** 20/99 **With/without aura:** 14/105 **Duration of migraine (months):** 91.8 (78.6) **Use of acute pain medication (n):** 40 **Previous use of acupuncture (n):** 2 **Yangming-specific**	**Both groups:** Acupuncture was applied unilaterally, alternating between the left and right sides. The goal was to elicit a de qi sensation in the three acupuncture groups but not in the sham-acupuncture group. Two types of Hwato needles (Suzhou Hua Tuo Medical Instruments, Suzhou, China) were used in all groups (length 25-40mm, diameter 0.25 mm; length 13mm, diameter 0.18mm). The patients received 20 treatments (30 min each) over a four week period: once per day for 5 consecutive days followed by a two-day break. Details published elsewhere. Patients were informed that they would receive one of four types of acupuncture treatment, three of which used traditional Chinese acupuncture theories	**intensity** (0-3 scale)	Final= 1.0 (0.9-1.3) p=0.002 **SN:** Baseline= 2.1 (2.0-2.2) Final= 1.4 (1.2-1.6) p=0.31 **Y:** Baseline= 2.0 (1.9-2.1) Final= 1.3 (1.1-1.5) p=0.17 **All*** Baseline= 2.03±0.55 Final= 1.23±1.12 **Sham:** Baseline= 2 (1.9-2.1) Final= 1.5 (1.3-1.8)	migraine days between Shaoyang-specific acupuncture and control groups, 105 patients per group were required. Block randomisation stratified by centre – block length unknown to centres. Patients, outcome assessors and statisticians were blinded to randomisation. All analysis based on ITT population in original study (number randomised who received at least one treatment session) Not able to interpret ACA figures
			MSQL restrictive	**Acupuncture:** **SS:** Baseline= 61.2 (58.7-63.7) Final= 81.9 (79.1-84.7) p<0.001 **SN:** Baseline= 58.5 (55.6-61.4) Final= 77.8 (75.1-80.6) p=0.01 **Y:** Baseline= 60.3 (57.9-62.7) Final= 77.3 (74.5-80.0) p=0.022 **All*** Baseline= 60.01±14.44 Final= 79.02±15.60 **Sham:** Baseline=58.5 (55.8-61.2) Final= 72.7 (70-75.5)	
			MSQL preventive	**Acupuncture:** **SS:** Baseline=70.5 (67.6-73.4) Final=87.2 (84.7-89.7)	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 118 randomised, 111 assessed **Dropouts:** 7 (4 reason unclear, 4 unsatisfied) **Age (mean):** 36.8 (13.0) **M/F:** 26/92 **With/without aura:** 12/106 **Duration of migraine (months):** 104 (100.7) **Use of acute pain medication (n):** 36 **Previous use of acupuncture (n):** 1 **Group 2 –sham** **N:** 118 randomised, 110 assessed	and one which was based on modern acupuncture theory. Patients were instructed not to take any regular medications for the treatment of migraines. In cases of severe pain, ibuprofen (300mg each capsule with sustained release) was allowed as rescue medication.		p<0.001 **SN:** Baseline=66.5 (63.1-69.9) Final=83.7 (81.2-86.1) p=0.019 **Y:** Baseline=69.5 (66.5-72.5) Final=71 (67.9-74.1) p=0.12 **All*** Baseline= 68.84±17.22 Final= 84.42±13.68 **Sham:** Baseline= 66.9 (63.4-70.4) Final= 79.5 (77.1-82)	
	Dropouts: 8(2 reason unclear, 4 unsatisfied, 2 other reason) **Age (mean):** 37.5 (12.1) **M/F:** 15/103 **With/without aura:** 12/106 **Duration of migraine (months):** 102 (93.4) **Use of acute pain medication (n):** 45 **Previous use of acupuncture (n):** 12		**MSQL functional**	**Acupuncture:** **SS:** Baseline=70.3 (66.9-73.7) Final=88 (85.1-90.8) p=0.008 **SN:** Baseline=67 (63.4-70.6) Final=83.7 (81-86.5) P=0.58 **Y:** Baseline=71 (67.9-74.1) Final=82.5 (79.8-85.3) p=0.96 **All*** Baseline= 69.43 ±18.7 Final= 84.76±15.54 **Sham:** Baseline= 69 (65.9-72.1) Final=82.6 (79.9-85.4)	
			Incidence of adverse events (not stated whether considered serious	**Acupuncture:** **SS:** 9 (6 subcutaneous haemorrhage, 1 subcutaneous haematoma, 1 subcutaneous ecchymosis, 1 leg weakness)	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
			or not, but all patients recovered fully)	**SN:** 8 (65subcutaneous haemorrhage, 3 subcutaneous haematoma) **Y:** 12 (10 subcutaneous haemorrhage, 2 subcutaneous haematoma) **All*** 29 **Sham:** 8 (4 subcutaneous haemorrhage, 4 subcutaneous ecchymosis)	

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval, SS=shaoyang specific, SN=Shaoyang non-specific, Y=yangming specific

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Linde et al, 2005[501] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** 18 outpatient centres **Duration of follow-up:** 24 weeks	**Patient group:** Adults with migraine with or without aura (IHS criteria) **Inclusion criteria:** Diagnosis of migraine, with or without aura, according to IHS criteria; 2-8 migraine attacks per month during the last 3 months and during the baseline period; aged 18-65yrs; had migraines for at least 12 months; completed baseline headache diary. **Exclusion criteria:** Interval headaches or additional tension-type headache on more than 10 days per month; inability to distinguish between migraine attacks and additional tension type headache' secondary headaches; start of headaches after age 50 years; use of analgesics on more than 10 days per month; prophylactic headache treatment with drugs during the last 4 weeks; any acupuncture treatment during the last 12 months or at any time if performed by the participating trial physician.	**Group 1 Acupuncture** Semi standardised developed by consensus of acupuncture experts – all treated at 'basic' points (gallbladder 20, 40 or 41 or 42, Du Mai-governing vessel 20, liver 3, San Jiao 3 or 5, extra point Taiyang) bilaterally unless explicit reasons for not doing so were given; additional points could be chosen individually according to patient symptoms. Sterile disposable 1-time-use needles had to be used but physicians could choose needle length and diameter. Physicians instructed to achieve 'de qi' if possible and to stimulate needles manually at least once during each session. Total number of needles was limited to 25 per session. **Group 2 Minimal acupuncture (sham)** Number, duration and frequency of the sessions were the same as for acupuncture group. In each session, at least five out of 10 predefined distant non-acupuncture points were needled bilaterally (at least 10 needles) and superficially using fine needles. De qi and manual	**Patient-reported migraine days** (mean (SD) baseline and final values)	**Wks 9-12** **Group1:** Baseline 8.3 (3.4)) Final 4.9 (3.4) **Group 2:** Baseline 8.3 (3.6) Final 4.7 (3.4) **Mean difference:** 0.1 **95% CI:** -0.8;1.1 **p value:** 0.76	**Funding:** Various social health insurance funds **Limitations:** Single blind (patients and assessors only) **Additional outcomes:** Days with moderate to severe headache Headache days Accompanying symptoms Days activities impaired Responder rate in terms of days of moderate to severe headache Modified version of German society for the study of pain questionnaire Pain Disability Index Emotional aspects of pain Depression scale Allgemeine Depressionskalla **Notes:** Most patients recruited through reports in local newspapers; some spontaneously contacted the trial centres.
			Patient-reported migraine days (mean (SD), baseline and final values)	**Week 24** **Group1:** Final 5.2 (3.3) **Group 2:** Final 4.8 (3.1) **Mean difference:** 0.4 **95% CI:** -0.6;1.3 **p value:** 0.42	
			Patient-reported migraine intensity (pain rating scale (scale not stated), baseline and final values, mean(SD))	**Week 12** **Group1:** Baseline 5.6 (1.6) Final 3.7 (2.0) **Group 2:** Baseline 5.6 (1.6) Final 3.6 (2.1) **Mean difference:** 0.1 **95% CI:** -0.5;0.6 **p value:** 0.87	
			Patient-reported migraine intensity (pain rating scale, baseline and final values, mean (SD))	**Week 24** **Group1**: Final 3.8 (2.1) **Group 2:** Final 3.4 (2.0) **Mean difference:** 0.4 **95% CI:** -0.2;1.0 **p value:** 0.24	
			Responder rate (50% reduction in	**Wks 9-12** **Group1:** 78/138 (56%*)	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	All patients N: 304 randomised (2 erroneously – did not return after baseline). **Group 1 – Acupuncture** **N:** 145 (randomised) 138 at 12 wks, 131 wk 24 **Age (mean):** 43.3 (11.8) **M/F:** 16/129 (11/89%) **With/without aura:** 40/109 (28/75%) **Disease duration (yr):** 20.9 (12.1) **Previous acupuncture:** 63 (43%) **Days medication needed (mean):** 5.0 (2.8)	stimulation of the needles were avoided. **Group 3 Waiting list** (not reported here) Both consisted of 12 sessions of 30 minutes given over 8 weeks (preferably 2 sessions in each of the first four weeks, followed by one session a week in the remaining four weeks). 4 weeks baseline phase. All patients were allowed to treat acute headaches as needed. Treatment had to be documented in the headache diary.	migraine days)	**Group 2:** 43/78 (55%*) **Mean Difference:** 1.01 **95% CI:** 0.79;1.31 **p value:** >0.99	* Calculated by NCGC
			Responder rate (50% reduction in migraine days)	**Week 24** **Group1:** 64/145 (44%) **Group 2:** 39/81 (48%) **Mean difference:** 0.92 **95% CI:** 0.69;1.23 **p value:** 0.58	
			Use of acute pharmacological treatment (days medication used, mean (SD))	**Wks 9-12** **Group 1:** Baseline 5.0(2.8) Final 3.2(3.0) **Group 2:** Baseline 4.8(2.6) Final 3.4 (2.9) **Mean diff:** -0.2 **95% CI:** -1.0;0.6 **p value:** 0.65	
	Medication use during baseline: triptans 28%, ergot 1%, analgesics 71%, combinations 21% **Drop outs:** wk 12 7 (3 unclear, 1 unsatisfied, 1 personal reasons, 1 moved, 1 lost to follow-up), At week 24, 7 lost to follow-up **Group 2 - Sham** **N:** 81 randomised, 78 at wk 12, 72 at wk 24		**Use of acute pharmacological treatment**	**Week 24** **Group1:** 3.6 (3.7) **Group 2:** 3.4 (2.5) **Mean diff:** 0.1 **95% CI:** -0.8;1.1 **p value:** 0.76	
			Functional health status and health-related quality of life (SF-36 physical health, baseline and	**Wks 9-12** **Group 1:** Baseline 41.6(7.7) Final 46.7(7.5) **Group 2:** Baseline 44.0 (6.6) Final 47.5 (7.0) **Mean diff:** -0.8	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	Age (mean): 41.3 (10.2) **M/F:** 8/73 (10/90%) **With/without aura:** 23/62 (28/77%) **Disease duration (mean, yrs):** 19.2 (11.7) **Previous acupuncture:** 30 (37%) **Days medication needed (mean):** 4.8 (2.6) **Medication use during baseline:** triptans 30%, ergot 2%, analgesics 79%, combinations 14% **Drop outs:** wk 12, 3 (2 unclear, 1 lost to follow-up) at wk 24 6 lost to follow-up		final values) Group1n=138, Group2=78	**95% CI:** -2.9;1.3 **p value:** 0.44	
			Functional health status and health-related quality of life (SF-36 mental health, baseline and final values)	**Wks 9-12** **Group1:** Baseline 47.6(10.1) Final 48.6 (8.8) **Group 2:** Baseline 47.2(10.0) Final 47.6 (9.6) **Mean diff:** 0.9 **95% CI:** -1.6;3.5 **p value:** 0.47	
			Functional health status and health-related quality of life (SF-36 physical health, baseline and final values)	**At week 24** **Group1:** Final 46.7 (7.0) **Group 2:** Final 48.8 (7.3) **Mean diff**: -2.1 **95% CI:** -4.2;0.0 **p value**: 0.05	
	Group 3 – Wait list control (not reported here)		**Functional health status and health-related quality of life** (SF-36 mental health, baseline and final values)	**At weeks 21-24** **Group1:** Final 49.4 (9.0) **Group 2:** Final 47.7 (9.8) **Mean diff:** 1.7 **95% CI:** -1.0;4.4 **p value:** 0.22	
			Incidence of serious adverse events (n)	**Group1**: 4 **Group 2:** 1 All hospital stays considered unrelated	

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval, IHS=International Headache Society