Tension type headache

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Ebneshahidi et al, 2005[244] **Study design:** RCT **Comparison:** Laser acupuncture vs sham laser **Setting:** 3 outpatient departments **Duration of follow-up:** 3 months	**Patient group:** Adults with chronic tension type headache **Inclusion criteria:** Chronic tension type headache for which the subject had not received any treatment in the previous two weeks. **Exclusion criteria:** Other causes of chronic headache. Patients with papilloedema, pulsating headaches, asymmetrical papillary reflexes, neurological deficits, systemic disorders (hypertension or metabolic disorders) or contraindications to treatment (anticoagulation therapy, other simultaneous treatment, localised skin infection, fear of acupuncture). **All patients:** **N:** 50 **M/F:** 40/10 **Drop outs**: 0 **Group 1 – Laser acupuncture** **N:** 25 **Age (mean):** 33 (25-52)	**Group 1 Laser acupuncture** Low energy laser radiation treatment from Endolaser 476. Gallium-Arsenide-Aluminium (Ga-As-Al). Output wave length of 830nm, max output intensity of 39mW/cm2 For each point: intensity 1.3J (~13 J/cm^2), output 100%, continuous mode, using vertical contact with pressure and a duration of 43 seconds. The points for exposure to laser radiation were selected by reference to authoritative sources on acupuncture. These included four points, two local and two distal: GB14, GB20, L14 and LU7. Treated bilaterally. **Group 2 Placebo laser acupuncture** Same intervention as above except that the power output was set to zero during the treatment. Both received three times per week for 10 sessions	**Change in patient-reported headache days** (Change from baseline – Median (IQR) at 3 months) **Change in patient-reported headache intensity** (VAS 0-10 Change from baseline – Median (IQR) at 3 months) **Incidence of serious adverse events (%)**	**Group1:** -8 (21.5) **Group 2:** 0 (0.0) **p value**: <0.001 **Group1:** -2 (6.3) **Group 2:** 0 (0.0) **p value:** <0.001 No AEs reported	**Funding:** NR **Limitations:** Patients selected consecutively by neurologists according to inclusion/exclusion criteria. States randomised, but no more details. Observer not blinded. Different methods of data collection used for baseline data vs follow-up (investigator assessment vs diaries) – possible measurement bias. **Additional outcomes:** Duration of attack (hours) All reported at 1,2 and 3 months **Notes:**

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	Migraine intensity (VAS): 10 (3.0) **Headache days (per month, median (IQR)):** 20 (15.0) **Group 2 – Placebo acupuncture** **N:** 25 **Age (mean):** 38.6 (26-54) P=0.04 cf Gp1 **Migraine intensity (VAS):** 10 (1.0) **Headache days (per month, median (IQR)):** **18** (15.0)	No concomitant analgesics allowed			Patients were naive to acupuncture Outcomes recorded in daily diaries. Powered for detecting 6 point difference in VAS.

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, IQR=inter-quartile range

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Endres et al, 2007[259] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** 122 family physician practices **Duration of follow-up:** 6 months	**Patient group**: Adults with IHS defined episodic or chronic tension type headache **Inclusion criteria:** Aged 18-65 with diagnosis of episodic or chronic tension type headache according to IHS criteria (in particular minimum frequency of 10 headache days per four weeks defined as a day on which headache lasts at least 4hr or when analgesics are taken for headache pain, in which case the headache pain could persist for less than four hours). **Exclusion criteria:** Duration of symptoms less than six months; >1 migraine headache day per four weeks; medication overuse headache or other secondary headache; other severe pain disorders; use of analgesics other than aspirin, paracetamol and NSAIDS; any change in pain medication during the previous 8 weeks; TTH prophylaxis during the previous 12 months; any acupuncture treatment during the previous 12 months; and prior use of acupuncture for headache.	**Group 1 Acupuncture** Consisted of fixed points used in all patients with additional points chosen individually by the physicians on the basis of traditional Chinese medicine diagnosis, including tongue diagnosis. Needles were inserted 2-30mm and manually stimulated to achieve De Qi. Neither electrical stimulation nor moxibustion were allowed. Patients were reassessed at each visit and chosen acupuncture points were modified if clinically indicated. **Group 2 Sham** Avoided all known verum points or meridians for needling; no points on the head could be used. Needles were inserted superficially (1-3mm) and were not stimulated, so as to avoid De Qi. **Both groups:** The number (10-25) and type of needles (sterile, single use needles, coated, 0.25-0.30mm thick, 25-40,, long) and number (10-15), length (30 min) and frequency (2/week) of treatment	**Patient-reported headache days** (baseline and final values per 4 weeks) N: Gp1 199, Gp2 192	**At 3 months** **Group1:** Baseline 15.6 (5.3) Final 6.8 (6.3) Group 2: Baseline 16.4 (6.1) Final 9.1 (8.0) **Between group difference**: 1.80 **95% CI:** 0.58;3.02 **p value**: 0.004	**Funding:** German public health insurance companies: AK, BKK, IKK, Bundesknappschaft, Bumdesverband de Landwirtschaftlichen Krankenkassen and Seekasse **Limitations:** Single blind (assessor and patient) A small number of patients in each group reported being unblinded by their physician, but only half of these correctly identified their allocation. Baseline differences between medication use. Study notes their different definition of responder rate may have affected results, therefore does a post-hoc analysis to calculate normal responder rate. **Additional outcomes:** Patient global assessment of therapy effectiveness (1-6 scale). Quality of acupuncture
			Patient-reported headache days (baseline and final values per 4 weeks) N: Gp1 204, Gp2 194	**At 6 months** **Group1:** Final 6 (6.2) **Group 2:** Final 8.4 (7.9) **Between group difference:** 1.94 **95% CI**: 0.69;3.18 **p value:** 0.002	
			Patient-reported headache intensity (Von Korff chronic pain grade scale (modified 3 month version) Mean (SD)/4 wks) N: Gp1 198, Gp2 191	**At 3 months** **Group1: Baseline 68.3 (12.1) Final 57.6 (17.2)** **Group 2:** Baseline 67.5 (12.5) Final 60.0 (16.3) **Between group difference:** 2.58 **95% CI:** -0.75;5.91 **p value:** 0.13	
			Patient-reported headache intensity (Von Korff chronic pain grade scale (modified 3 month version) Mean (SD)/4	**At 6 months** **Group1:** Final 53.5 (18.4) **Group 2:** Final 56.7 (19.6) **Between group difference: 3**.24 **95% CI**: -0.51;6.99	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	All patients **N:** 413 randomised (4 to amitriptyline group) **Group 1 – Acupuncture** **N:** 209 (randomised) 208 (received treatment) **Age (mean):** 39.2 (11.4) 30-47 **M/F:** 46/163 (22 vs 78%) **Duration of TTH (yrs):** 11.2 (10.3) 4.1-15.4 **TTH days/4wks (median):** 14 (12-18) **TTH type:** 56% episodic 44% chronic **Drop outs:** 1 (refused) **Missing data:** 5 **Group 2 - Sham** **N:** 200 (randomised) 195 (received treatment)	sessions were the same. Investigators were instructed to treat patients in each group identically other than the placement of needles. Rules for point selection and Chinese diagnosis were established on the basis of international literature and a consensus process. All patients could receive an additional 5 sessions if they experienced a reduction in headache days per 28 days of at least 20% but no more than 50%. This was assessed in a telephone interview after 10 sessions. During the study patients were allowed to take only one of their pre-baseline oral headache analgesics. They were not allowed to change this analgesic.	wks) N: Gp1 204, Gp2 194	**p value:** 0.09	treatment. Patient blinding. Medication use as: none, 1, >1, >15days. **Notes:** Trial initially included an arm receiving treatment with amitriptyline, however poor early accrual was ascribed to patient unwillingness to receive antidepressant medication and independent data and safety monitoring committee recommended that this arm be dropped after one year (only 4 patients included). Most patients recruited through adverts in local newspapers and reports on radio and television. A minority spontaneously sought out a trial physician. Daily diaries kept to record outcomes as well as blinded telephone interviews.
			Responder rate (50% reduction in headache days ICH criteria)	**At 3 months** **Group1:** 119/199 (60%) **Group 2:** 91/192 (47%) **Absolute risk difference: 12**% **95% CI** 3-22% **p value:** 0.014	
			Responder rate (50% reduction in headache days ICH criteria)	**At 6 months** **Group1: 135/204 (66%)** **Group 2:** 106/194 (55%) **Absolute risk difference:** 12% **95% CI:** 2-21% **p value:** 0.024	
			Responder rate (50% reduction in headache days † see notes)	**At 6 months** **Group1:** 68/209 (33%) **Group 2:** 53/200 (27%) **Absolute risk difference:** 6% **95% CI** -3-15% **p value:** 0.18	
	Age (mean): 38.9 (12.2) 29-48 **M/F:** 42/158 (21 vs 79%) **Duration of TTH (yrs):** 11.7 10.7) 3.1-18.3 **TTH days/4wks (median):** 14 (12-19) **TTH type:** 53% episodic 47% chronic **Drop outs**: (2 refused, 3 did not return)		**Quality of life** **SF-12 physical component** (Baseline and Final values, mean(SD)) Gp1 n=199, Gp2=188	**At 3 months** **Group1: Baseline 39.6 (8.1) Final 46.8 (8.1)** **Group 2:** Baseline 41.8 (8.1) Final 46.5 (8.3) **Between group difference:** 1.06 **95% CI:** -0.45;2.57 **p value**: 0.17	
			Quality of life	**At 3 months**	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	Missing data: 9		**SF-12 mental component** (Baseline and Final values mean (SD))	**Group 1:** Baseline 45.9 (10.3) Final 50 (9.1) **Group 2:** Baseline 46.1 (10.1) Final 50.2 (9) **Between group difference:** -0.10 **95% CI:** -1.65;1.46 **p value:** 0.90	† Responder was defined as >50% reduction in number of headache days/ 4 weeks, however if one of the following criteria applied the patients were characterised as non-response regardless of whether a reduction of >50% had been achieved: patient unblinding, excluded concomitant treatments, injections (except vaccinations insulin, heparin), wrong acupuncture treatment (, median number of needles more or fewer than the permitted 10-25 per session, treatment cessation or any change of analgesics.
			Quality of life **SF-12 physical component** (Baseline and Final values (mean (SD))	**At 6 months** **Group1:** Final 47.1 (8.1) **Group 2:** Final 46.5 (8.6) **Between group difference:** 1.38 **95% CI:** -0.17;2.92 **p value:** 0.08	
			Quality of life **SF-12 mental component** (Baseline and Final values, mean (SD))	**At 6 months** **Group 1:** Final 50.6 (8.4) **Group 2:** Final 50.8 (9.2) **Between group difference: 0**.05 **95% CI**: -1.48;1.58 **p value:** 0.95	

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, TTH=tension type headache, IHS=International Headache Society

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Karst et al, 2001[422] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** NR, assumed outpatients **Duration of follow-up:** 5 months post treatment (~6 months total)	**Patient group:** Adults with episodic or chronic tension type headache **Inclusion criteria:** Episodic or chronic tension type headache according to IHS classification. **Exclusion criteria:** Anticoagulation, predominantly operating factors (e.g. secondary gain, compensation, disability and psychosocial factors), rebound analgesic headache syndrome, symptomatic or other concomitant headache. Patients with past or present episodes of migraine. **All patients** N: 69 **Group 1 – Acupuncture** **N:** 34 **Age (mean):** 47.9 (13.8) **M/F:** 17/17 **Episodic / chronic:** 9/25 **Mean headache days/month:** 21.1 (10.2) **Analgesics/month:** 9.0 (11.1) **Drop outs:** NR **Group 2 - Sham** **N:** 35	**Group 1 Acupuncture** Seirin B-type needles no.8 (0.3x0.3mm) and no.3 (0.2x0.15mm) used **Group 2 Sham** The tip of the needle is blunt in order to cause a pricking sensation without actually puncturing the skin. The needle was inserted through a cube-shaped elastic foam to obscure the patients' vision on the insertion point. Both groups had two treatments per week for a total of 10 treatments. Needles inserted at acupoints GB20, LI4 and LR3 and depending on the symptoms at acupoints GB8, GB14, GB21, GB41, UB2, UB10, UB60, LU7, TW5, ST8, ST36, ST44, DU20 and Extra1. A maximum of 15 needles were inserted but treatment was usually carried out with not more than 6-10	**Patient-reported headache frequency** (Days per month, mean (SD)) **Patient-reported headache intensity** (Pain intensity, 0-10 VAS, mean of 4 weeks, mean (SD)) **Functional health status and health-related quality of life** (Nottingham Health Profile mean (SD)) **Functional health status and health-related quality of life** (Everyday Life Questionnaire, mean (SD)) **Functional health status and health-related quality of life**	**At 5months post** **Group1:** Baseline 21.1 (10.2) Final 16.7 (12.0) **Group 2:** Baseline 20.5 (10.3) Final 17.2 (12.0) **p value:** NS **6 weeks post (almost 3mo)** **Group1:** Baseline 4.6 (1.8) Final 4.0 (1.9) **Group 2:** Baseline 4.4 (1.3) Final 4.6 (1.7) **p value:** NS **6 weeks post (almost 3mo)** **Group1**: Baseline 29.9 (7.2) Final 34.1 (4.5) **Group 2:** Baseline 28.6 (5.7) Final 31.4 (5.4) **p value:** NS **6 weeks post (almost 3mo)** **Group1:** Baseline 114.7 (25) Final 132.1 (20.6) **Group 2:** Baseline 116.1 (23.8) Final 127.8 (23.7) **p value:** NS **6 weeks post (almost 3mo)** **Group1:** Baseline 5.6	**Funding:** NR **Limitations:** Randomisation unclear. Single blind (patients and assessors) Incomplete outcome reporting (QoL measures not reported at 5 months) **Additional outcomes:** Pain intensity (VAS) Site and duration of headache attack CGI (VAS) Freiburg Questionnaire of coping with illness Von Zerssen Depression Scale

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	Age (mean): 48.2 (14.6) **M/F:** 14/21 **Episodic / chronic:** 12/22 **Mean headache days/month:** 20.5 (10.2) **Analgesics/month:** 15.6 (32.4) **Drop outs:** NR	needles. The needles were left in place for 30 min after insertion. Concomitant medication (including analgesics and rescue medications) allowed but had to be reported.	(Life Quality Scale (0-10) mean (SD))	(2.2) Final 6.6 (2.0) **Group 2:** Baseline 5.2 (2.6) Final 6.5 (2.2) **p value:** NS	
			Use of acute pharmacological treatment (no. analgesics per month, mean (SD))	**6 weeks post (almost 3mo)** **Group1:** Baseline 9.0 (11.1) Final 5.3 (9.0) **Group 2:** Baseline 15.6 (32.4) Final 26.0 (74.0) **p value:** NS	

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, QoL=quality of life, NS=Not significant, IHS=International headache society, CGI=clinician global impression, VAS=visual analogue scale

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Melchart et al, 2005[553] **Study design:** RCT **Comparison:** Acupuncture vs sham **Setting:** 28 outpatient centres **Duration of follow-up:** 24 weeks	**Patient group:** Adults with episodic or chronic tension type headache **Inclusion criteria:** Diagnosis of episodic or chronic tension-type headache according to IHS criteria, at least 8 days with headache a month in the previous three months and in the baseline period, age 18-65 years, duration of symptoms at least 12 months, completed baseline headache diary and written informed consent. **Exclusion criteria:** Additional migraine headache, secondary headaches, start of headaches after age 50, use of analgesics on more than 10 days a month, prophylactic headache treatment with drugs during the previous four weeks, and any acupuncture treatment during the previous 12 months or at any time if done by the participating trial physician. **All patients** **N:** 296 randomised (26 excluded in 1 trial centre) **Drop outs:** 26 – one trial centre	**Group 1 - Acupuncture** Semi standardised – all treated at 'basic' points bilaterally unless explicit reasons for not doing so were given; additional points could be chosen individually. 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)** Physicians needled at least five out of 10 predefined distant non-acupuncture points bilaterally (at least 10 needles) and superficially using fine needles. Physicians avoided 'de qi' and manual stimulation of the needles. **Group 3 - Waiting list (not reported here)** Both groups: Consisted of 12 sessions of	**Patient-reported headache days** (baseline and final values, Mean (SD)) **N** Gp1=118, Gp2=57 at week 12 **N** Gp1=112, Gp2=55 at week 24	**Wk 9-12** **Group1: Baseline 17.5 (6.9)** Final 9.9 (8.7) **Group 2:** Baseline 17.7 (6.7), Final 10.8 (8.3) **Change difference between groups**=0.6 days, 95% CI: -1.5, 7.2 **P**<0.001 **Wk 21-24** **Group1:** Final 10.4 (8.6) **Group 2:** Final 11.2 (8.6)	**Funding:** Various social health insurance funds **Limitations:** Groups were not comparable at baseline for all outcomes – especially in previous use of acupuncture. Trial physicians couldn't be blinded, but assessors were. **Additional outcomes:** Hours with headache, headache score, days with more than mild headache, disability (PDI), Pain affective and sensoric (SES standard scores), average pain on 1-10 scale. Details of mild side effects. **Notes:** Most participants recruited through reports in local newspapers; a minority were patients who spontaneously contacted trial centres. 1 study centre excluded from analysis (before analysis started) n=26. Due to repeated severe protocol violations and suspicion of
			Patient-reported headache intensity (Average pain scale 0-10, baseline and final values, mean (SD)) **N Gp1=118, Gp2=57 at week 12** **N** Gp1=112, Gp2=55 at week 12	**Wk 9-12** **Group1:** Baseline 30.0 (13.5) Final 15.8 (15.3) **Group 2:** Baseline 29.9 (14.1), Final 17.2 (14.4) **Change difference between groups =-**0.8 days, 95% CI: -4.4;2.7 P=0.64 **Wk 21-24** Group1: Final 17.6 (16.7) Group 2: Final 18.6 (16.2)	
			Change in patient-reported headache intensity (Headache score, sum of intensity ratings (1-3) of days with headache, baseline and final	**Wk 9-12** **Group1: Baseline 4.5 (1.5)** Final 2.9 (1.6) **Group 2:** Baseline 4.9 (1.5), Final 3.1 (1.7) **Change difference between groups** =-0.1 days, 95% CI: -	

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	excluded, 25 for various reasons **Group 1 – Acupuncture** **N:** 132 randomised, 124 with week 12 data, 114 week 24 **Age (mean(SD)):** 42.3 (13.5) **Drop outs:** Wk 12: 6 (1 didn't tolerate needles, 1 private reasons, 4 other) 2 lost to follow up. Wk 24 10 lost to follow up **TTH type:** 57% episodic, 43% chronic **Previous acupuncture:** 46 (35%) **Duration of disease (yrs):** 13.7 (11.1) **Days with headache*:** 17.5 (6.9) **Days with medication*:** 4 (3.7) **SF-36:** Physical; 42.9 (7.2) Mental; 45.6 (10.5) **Group 2 – Minimal acupuncture** **N:** 63 randomised, 59 with week 12 data, 56 for week 24 **Age (mean(SD)):** 43.4 (12.9) **Drop outs:** Wk 12: 1 (intercurrent disease) 3 lost to follow up, Wk 24: 3 lost to follow up **TTH type:** 49% episodic, 51% chronic	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.	values, mean (SD)) **N** Gp1=119, Gp2=58 at week 12 **N** Gp1=113, Gp2=54 at week 12	0.6;0.4 P=0.77 Wk 21-24 **Group1:** Final 2.8 (1.8) **Group 2:** Final 3.1 (1.8)	data-manipulation by some patients. Most commonly reported side effects were triggering of headache or other pain, haematoma and dizziness. Study states there were differences in guesses about treatment allocation at the end of trial which might indicate some degree of unblinding – 63/127 guessed in the acupuncture group and 20/63 in the minimal acupuncture group. * Calculated by NCGC
			Functional health status and health-related quality of life (SF-36)	**Wk 9-12** **Group1:** Physical baseline; 42.9 (7.2) Final 48.2 (7.5) Mental baseline; 45.6 (10.5) Final 47.4 (9.8) **Group 2:** Physical baseline; 44.3 (6.8) Final 49 (6.1) Mental baseline; 44.1 (12.1) Final 46.1 (11.8) **Wk 21-24** **Group1: Physical Final 48.1 (6.9)** Mental Final 47.2 (10.3) **Group 2:** Physical Final 49.1 (5.4) Mental Final: 47.6 (10.1)	
	Previous acupuncture: 34 (54%) **Duration of disease:** 16.8 (13.8)		**Responder rate** (50% reduction in headache days) Those with no data counted as non-responders	**Wk 9-12** **Group1: 46% (61/132*)** **Group 2:** 35% (22/63*) **p value:** 0.163	
			Use of acute pharmacological	**Wk 9-12** **Group1: baseline 4 (3.7)**	

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	Days with headache*: 17.7 (6.7) **Days with medication*:** 4.2 (4.2) **SF-36:** Physical; 44.3 (6.8) Mental; 44.1 (12.1)		**treatment** (days with analgesic use)	Final 1.9 (2.9) **Group 2:** Baseline: 4.2 (4.2) Final 2.6 (2.6) Wk21-24 **Group1 Final:** 2.3 (4.0) **Group 2 Final:** 2.9 (3.5)	
			Incidence of serious adverse events (%)	**Group1:** 2 **Group 2:** 1 (All hospital stays considered unrelated to the study)	

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