Tension type headache

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Bove & Nilsson, 1998[102] **Study design:** RCT **Comparison:** Spinal manipulation vs placebo **Setting:** Outpatient facility of Chiropractic research institution in Denmark **Duration of follow-up:**	**Patient group:** Adult patients (20-60 years) fulfilling IHS criteria for Episodic Tension Type Headache (ETTH). **Inclusion criteria:** Fulfilled IHS criteria for ETTH with more than 5 but fewer than 15 headache episodes per month; age 20-60 years; score for typical headache intensity between 25 and 85 on visual analogue scale from 0 to 100; no relative or absolute contraindications to manipulation. **Exclusion criteria:** After inclusion, participants could be excluded for any adverse reaction to treatment or any event triggering or potentially triggering a change in headache status (e.g. vehicular crash or neck injury). **All patients** **N:** 75 (randomised) **Age (mean):** 38 (range 20-59) **Drop outs:** 5 **Group 1** – Spinal manipulation + soft tissue therapy **N:** 38 (randomised); 36 (completed trial) **Age (mean):** 37 (range 22-59) **Drop outs**: 2 **Pharm treatment:** Usual pattern of medication continued	**Group 1 Spinal manipulation + soft tissue therapy** Manipulation group received joint manipulations of the cervical spine as determined by chiropractor and also deep friction massage. **Group 2 Placebo (Laser+ soft tissue therapy)** Control group received deep friction massage and application of low-power laser light to upper cervical region (effect reported to be equal to placebo). Weeks.1 and 2: Baseline data collected Weeks 3-6: Randomised patients treated 8 times, usually twice a week. Post treatment data was collected from patients' headache diaries completed during weeks 7, 11, 15 and 19.	**Patient-reported headache intensity** [Mean headache intensity, (95%CI)] Intensity calculated on Visual analogue scale 0-100	**Group 1** Baseline: 37 (33-41); SD = 12.17* Week 15:29 (23-35) SD = 18* **Group 2:** Baseline: 37 (33-41) SD = 12* Week 15: 33 (25-41) SD = 23.64* **p values:** 2vs 1 (baseline): 0.89 2vs 1 (week 15): 0.41	**Funding:** Nordisk Institut for Kiropraktik og Klinisk Biomekanik (Odense, Denmark) **Limitations:** Unclear randomisation and allocation concealment. No blinding of care administrators. No information on validation of headache diaries used. **Additional outcomes:** Mean headache hours per day. **Notes:** All patients continued usual pattern of medication. *Calculated at NCGC
			Use of acute pharmacological treatment (Mean number of analgesics per day, 95%CI)	**Group1:** Baseline: 0.66 (0.49-0.83) SD = 0.52* Week 15: 0.48 (0.34-0.62) SD = 0.42* **Group 2:** Baseline: 0.82 (0.50-1.14) SD = 0.96* Week 15: 0.60 (0.26-0.94) SD = 1.00*	

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19 weeks	**Group 2** – Placebo (Laser+ soft tissue therapy) **N:** 37 (randomised); 34 (completed trial) **Age (mean):** 38 years (range 20-58) **Drop outs:** 3 (1 did not receive treatment, 2 lost to follow up) **Pharm treatment:** Usual pattern of medication continued.			**p values:** 2vs 1 (baseline):0.38 2vs 1 (week 15): 0.51	

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, ETTH= Episodic Tension Type Headache, IHS=International Headache Society

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Carlsson et al, 1990[132] **Study design:** RCT **Comparison:** Physiotherapy v Acupuncture **Setting:** Outpatient clinics in Departments of Neurology and Neurosurgery, Sahlgrenska hospital, Sweden **Duration of follow-up:** Unclear	**Patient group:** Female patients with chronic tension headaches **Inclusion criteria:** Female; aged 18-60 years; had chronic tension headache. **Exclusion criteria:** Presence of malignant or other serious diseases; headaches which had started in close temporal relation to an organic disorder; difficulty in understanding and speaking Swedish; patients with generalized myalgia and headache as part of a fibromyalgic syndrome. **All patients** **N:** 62(randomised); 52 (completed study) **Age (mean):** 34 years **Drop outs:** 10 **Group 1** – Physiotherapy **N:** 31 (randomised), 23(completed) **Age (mean):** NR **Drop outs**: 8 **Group 2** - Acupuncture **N:** 31(randomised);	**Group 1 – Physiotherapy** Treatment extended over 2-3 months (10-12 sessions), with 1-2 sessions per week, each with 30-45 min of individual instruction. Treatment involved: teaching the patient to handle any situation with as little physical tension as possible and to avoid causative factors of headache; teaching the patient that pain relief could be obtained without analgesics massage, cryotherapy, and TENS which were used and managed by the patient herself; relaxation of the whole body performed according to a technique presented by Jacobsen including two 10 min sessions of daily training at home. Contracted and tender muscles were contracted heavily for 10 seconds and relaxed for 10 seconds and then passively stretched for 20 seconds. Patient was taught to practice relaxation in everyday life. **Group 2 – Acupuncture** Acupuncture was performed by two physicians using the same technique. Standard 1.5 inch stainless steel electrodes were used and needles were inserted perpendicularly to a depth where the sub cutaneous 'De Chi' phenomenon occurs. In all patients local points [GB20, GB21] and one distal point [LI 4] were treated. In patients with a probable migrainous component, the following additional points were used: GB14, the extra points Tai Yang in the	**Change in patient-reported headache intensity** [reported on a five point scale, mean(SD)]	**Group 1** Baseline: 3.72(0.73) After treatment: 2.52(0.80) Change: -1.21 **Group 2** Baseline: 3.78(0.96) After treatment: 3.24(1.04) Change: -0.54(1.01)	**Funding:** Grants from Renee Eanders Hjalpfond and the Swedish fund for scientific research without animal experiments **Limitations:** Unclear randomization and allocation concealment Unblinded trial-high degree of performance bias likely Different loss to follow up in both groups Treatment administered by study authors/investigators Treatment and follow up duration unclear: Initial assessments at 3-8 weeks before start of treatment, treatment period reported 10-12 weeks in physiotherapy group, 8-10 weeks in acupuncture group; Follow up assessments at 4-9 weeks after treatment termination. **Additional outcomes:** Muscle tenderness Cervical spine mobility **Notes:** 23 patients had a combination of migraine and tension

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	29(completed study) **Age (mean):** NR **Drop outs:** 2	temporal region and Yin Tang between the eyebrows. Needles were inserted and twiddled by hand at the first session and electrical stimulation via the needles was used from the second treatment on. Electrical parameters used were frequency 1-2 Hz, pulse width 0.5 milliseconds and intensity in the range of 4-7 volts. Length of each treatment was at least 20 min. Patients were advised to reduce their intake of analgesics as much as possible. 4-5 treatments were performed over a trial period and further treatments were given only if patients reported clear pain relief.			headache, with a clear predominance of tension headache. (Group not specified). 28 patients had taken analgesics exclusively for headaches before. 20 patients had taken analgesics and some other therapy such as relaxation programmes, TENS, zone therapy, ultrasound or acupuncture. (Group not specified).

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, TENS= Transcutaneous electrical nerve stimulation

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Castien et al, 2011[137] **Study design:** RCT **Comparison:** Manual therapy vs Usual care **Setting:** Multicentre trial (38 GP practices in the Netherlands) **Duration of follow-up:** 26 weeks	**Patient group:** Adults with chronic tension type headache (CTTH) **Inclusion criteria:** 18-65 years of age; fulfilled IHS criteria for CTTH; headache occurred on at least 15 days on average per month for a period of more than 3 months; headache lasted for hours or was continuous; Headache had at least one of the following characteristics: bilateral location, pressing/tightening(non-pulsating) quality, mild or moderate intensity, not aggravated by normal physical activity; had both the following characteristics; no more than one of photophobia, phonophobia or mild nausea, neither moderate or severe nausea nor vomiting. **Exclusion criteria:** Presence of rheumatoid arthritis, suspected malignancy, pregnancy, intake of either triptans, ergotamines or opioids on ≥10 days/month or simple analgesics on ≥15 days per month on a regular basis for ≥3 months; received manual therapy in the 2 months before enrolment into the study; not able to read and write Dutch. **All patients** **N:** 82 (randomised) **Drop outs:** 7 **Group 1 –** Manual therapy **N:** 41 (randomised); 40 (received treatment); 38 (present at follow up at 26 weeks) **Age (mean):** 40.2 (range 20-59) **Drop outs:**3	**Group 1 Manual therapy** Combination of mobilisations of the cervical and thoracic spine, exercises and postural correction specifically chosen for the management of cervicogenic headache Duration of each treatment session was 30 min; maximum of 9 treatments Type of techniques and exercises decided by manual therapist at each session **Group 2 Usual care** Treatment by GP according to Dutch general practice guideline for management of headache (included information, re-assurance and advice, and if required prescription of analgesics/NSAIDs or changing current medication)	**Change in patient-reported headache days** [mean change(SD)at 26 weeks]	**Group 1:** -9.1(4.2) **Group 2:** -4.1(4.4) **Between group mean difference:** -4.9(0.99) **95% CI:** -6.95 to -2.98 **p value:** <0.001	**Funding:** NR **Limitations:** Unclear randomisation. No blinding of participants and care administrators. **Additional outcomes:** Sick leave taken up to 26 weeks. Headache Disability Inventory. Cervical range of movement. Endurance neck flexor. **Notes:** Amitriptyline was prescribed as a rescue medication to two patients but not reported in which group.
			Change in patient-reported headache intensity [mean change(SD) in average pain intensity on a 0-10 numeric rating scale at 26 weeks]	**Group 1:** -3.1(2.8) **Group 2:** -1.7(2.5) **Between group mean difference:** -1.4(0.63) **95% CI**: -2.69 to -0.16 **p value:** 0.027	
			Headache specific QoL [HIT 6-reported as mean change (SD) at 26 weeks]	**Group 1:** -10.6(8.4) **Group 2:** -5.5(8.6) **Between group mean difference:** -5.0(1.97) **95% CI**: -9.02 to -1.16 **p value:** 0.012	
			Responder rate (50% reduction in headache frequency at 26 weeks)	**Group 1:** 81.6% (31/38) **Group 2:** 40.5% (15/37) **Relative risk:**2.0 **95% CI:** 1.3 to 3.0)	

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	Pharm treatment: 41.5% (analgesics); 70.7%(NSAIDs) **Number of years with headache (mean, SD):** 12.5, 10.7 **Group 2 –** Usual care **N:** 41 (randomised); 40 (received treatment); 37 (present at follow up at 26 weeks) **Age (mean):** 40.6 (range 20-63) **Drop outs:**4 **Pharm treatment:** 41.5%(analgesics); 65.9% (NSAIDs) **Number of years with headache (mean, SD):** 13.1, 12.3		**Resource use** (Use of additional medical specialists at 26 weeks)	**Group1:** 1 (2.6%) **Group 2:** 6(16.2%) **Difference:**13.5% **95% CI:** 0.7-26.5%	
			Resource use (Use of additional health care-other than hospital attendance or medical specialists at 26 weeks)	**Group1:** 3 (7.8%) **Group 2:** 1(2.7%) **Difference:**5.1% **95% CI:** -4.8-15.2%	

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, CTTH =Chronic tension type headache, NSAIDs: Non-steroidal anti-inflammatory drugs

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Söderberg et al, 2006[745] **Study design:** RCT **Comparison:** Manual therapy (physical training) v Acupuncture v Psychological therapy (Relaxation training) **Setting:** Physiotherapy primary care units in Sweden **Duration of follow-up:** 2.5 to three months(treatment); follow up till six months after treatment	**Patient group:** Adults with a diagnosis of chronic tension type headache (CTTH) **Inclusion criteria:** Aged 18-65 years, diagnosed with CTTH according to IHS criteria, had tension headaches for at least 15 days for at least 6 months. **Exclusion criteria:** Headache that began after the age of 50 years; migraine more than once a month during the last year; inability to speak or read Swedish; serious somatic or psychiatric disease; drug abuse or use of analgesics and triptans >10 days per month. **All patients** **N:** 90 (randomised) **Age (median, range):** 37.5, 18.0-59.0 **Group 1 –** Manual therapy-Physical training **N:** 30 (randomised), 30 (Completed), 26 (three months after treatment), 19 (six months after) **Age (median, range)**: 35.9, 18.0-56.0 **Drop outs:** 11 **Headache duration in years (median, range):** 5.0, 2.0-30.0	**Group 1 – Manual therapy-Physical training** Training was performed by five registered physiotherapists. Patients performed two 45 minute training sessions a week at the clinic for 5 weeks and then a home training programme three times a week three times a week for 5 weeks (total of 25 sessions). Each training session consisted of 5 exercises repeated 35 times and three sets of each. Exercises focused on neck and shoulder muscles. Patients rested for 1-2 minutes between exercises. **Group 2 – Acupuncture** Acupuncture was done by five registered physiotherapists who had long experience in treating patient with acupuncture. Disposable needles with a dimension of 15x0.25 mm and 30 or 40x0.30 mm were used. Needles were inserted to a depth of 2-5 mm or 10-30 mm depending on location. Needles were twilled by hand until the patient felt the characteristic 'de qi' sensation. Mandatory points to be needled were GB 20, GB 14, LI 4, ST 44; Optional points were PC 6, PC 7, SP 6, GB 34, ST 8, EX 2 and EX 1. Treatment comprised of 10-12 sessions	**Patient-reported headache intensity** (reported on a VAS scale of 0-100)	**Group 1:** N=30 **Baseline Mean:** 22.03, **Median:** 19.26 **Range:** 4.66-48.20 Immediately after last treatment **Mean:** 15.50 **Median:** 14.82 **Range:** 0.30-51.53 3 months after last treatment **Mean**: 16.88 **Median:** 10.75 **Range:** 0.00-56.75 **Group 2:** N=30 **Baseline Mean:** 26.75 **Median:** 23.41 **Range:** 0.72-69.60 Immediately after last treatment **Mean:** 21.21 **Median:** 16.42 **Range:** 0.93-72.45 3 months after last treatment **Mean:** 18.93 **Median:** 12.34 **Range:** 0.00-53.38	**Funding:** Grants from Vardalsstiftelsen, Kommunala Landstingsangelagenheter, the Renee Eanders Fond, and GlaxoSmith Kline. **Limitations**: Unclear randomization and allocation concealment. No blinding of participants, care administrators. Blinding of investigators unclear. **Additional outcomes**: Headache- free periods Headache-free days

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	Group 2 - Acupuncture **N:** 30 (randomised), 30 (Completed), 27 (three months after), 17 (six months after) **Age (median, range):** 35.0, 18.0-59.0 **Drop outs**: 13 **Headache duration in years (median, range):** 10.0, 2.0-35.0 **Group 3 –** Psychological therapy-Relaxation training **N:** 30 (randomised),30 (Completed), 26 (three months after), 19 (six months after) **Age (median, range):** 43.5, 22.0-59.0 **Drop outs:** 11 **Headache duration in years (median, range):** 10.0, 2.0-37.0	during a period of 10-12 weeks. **Group 3 – Psychological therapy-Relaxation training** Relaxation was performed by three registered physiotherapists who had long experience and documented skills for treating patient with relaxation training. Relaxation training programme described by Larsson and Daleflod and based on progressive and autogenic relaxation techniques was used. The group also practised progressive relaxation training(by Jacobson), autogenic relaxation training (by Schultz), relaxation and breathing techniques, stress coping techniques and techniques to relax during activity and everyday living. Eight to ten sessions of relaxation training were performed individually under the supervision of a physiotherapist once a week. Patients received an audiotape which included the last session and were instructed to train at home once daily.		**Group 3: N=**30 **Baseline** **Mean: 26.14** **Median:** 20.05 **Range:** 3.77-61.71 Immediately after last treatment **Mean:** 16.77 **Median:** 15.61 **Range:** 0.00-56.24 3 months after last treatment **Mean:** 16.14 **Median:** 11.74 **Range:** 0.00-66.64	

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