Migraine

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Nelson et al, 1998[586] **Study design:** RCT **Comparison:** Manual therapy (Spinal manipulation) v TCA (Amitriptyline) **Setting:** Chiropractic college outpatient clinic, USA **Duration of follow-up:** 16 weeks	**Patient group**: Adults with migraine. **Inclusion criteria**: Diagnosis of migraine with/without aura; 18-65 years of age; history of migraine headaches for at least 1 year and had at least 4 headache days per month; diagnosis of migraine headache made according to IHS criteria. **Exclusion criteria:** Pregnancy or lactation; patients under active chiropractic or medical care (e.g., taking prescription medication) within the last month; inability to attend study appointments twice a week for 8 weeks; any clinical contraindication to spinal manipulative therapy (e.g., joint instability, fractures, inflammatory disease or amitriptyline therapy (e.g., cardiac arrhythmias, glaucoma, epilepsy). **Group 1** – Spinal manipulative therapy **N:** 77 (randomised); 77 (received treatment); 59 (completed treatment) **Age in years (mean):** 36.1 (11.4)	**Group 1 Spinal manipulative therapy** Patients were treated a total of 14 times over 8 week period, with no more than 2 treatments per week by chiropractors. Spinal manipulation administered was a type describes as high-velocity, low amplitude, short-lever arm. Chiropractors treated levels of the cervical or thoracic spine for which there were clinical indications (determined by motion and static palpation and findings of localised tenderness). **Group 2 Amitriptyline** 25 mg in first week of treatment, followed by 50 mg in second week, 75 mg in third week and a maximum of 100 mg after three weeks of therapy. Patients were seen three times during treatment period. **Group 3- Combined treatment** Patients simultaneously	**Change in patient-reported headache days** [% of days with headache, mean(SD)] 4 weeks post treatment	**Group 1** n=58 Baseline: 55.1 (26.3) Final: 36.9 (29.3) **Group 2** n=47 Baseline: 51.8 (24.4) Final: 40.5(23.3) **Group 3** n=54 Baseline: 30.9 (22.8) Final: 39.9 (26.6)	**Funding:** Foundation for Chiropractic Education and Research Grant # 92-03-06 **Limitations:** Unblinded trial 5 patients from pharmacological group did not accept treatment allocation and dropped out of the trial. Different reasons for loss to follow up in both groups. Patient expectation of improvement immediately after randomization differed significantly between groups. **Additional outcomes:** Headache index calculated as the weekly sum of each patient's headache pain scores. **Notes:** All patients allowed to use over the counter medication as necessary.
			Change in patient-reported headache intensity [reported on a scale of 0-10, mean(SD)] 4 weeks post treatment	**Group 1** n=56 Baseline: 5.0 (1.3) Final: 4.4 (1.7) **Group 2** n=44 Baseline: 4.6 (1.1) Final: 4.5 (1.3) **Group 3** n=50 Baseline: 4.4 (1.1) Final: 4.3 (1.4)	
			Functional health status and health-related quality of life [SF-36 on 0-100 scale, mean(SD)] 4 weeks post treatment	**Group 1** n=58 Baseline: 67.1(14.5) Final:74.4 (15.1) **Group 2** n=50 Baseline: 66.3(13.4) Final: 71.5 (12.4) **Group 3** n=55 Baseline: 64.3 (15.7) Final:71.9 (14.1)	
			Use of acute pharmacological treatment	**Group 1** n=58 Baseline: 2.2(1.9) Final: 1.2(1.2)	

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	Drop outs: 18 (lost to follow up) **Group 2** - Amitriptyline **N:** 70 (randomised); 65 (received treatment); 49 (completed treatment) **Age in years (mean):** 37.4 (10.9) **Drop outs:** 20 (5 refused treatment allocation, 7 side effects, 8 lost to follow up) **Group 3**- Combined treatment **N:** 71 (randomised); 71 (received treatment); 56 (completed treatment) **Age in years (mean):**40.2 (9.8) **Drop outs:** 17 (13 lost to follow up, 4 had side effects)	received both spinal manipulative therapy and amitriptyline therapy for the 8 week treatment period. 4 week baseline period, followed by 8 week treatment period, followed by 4 week follow up period. Patients kept a daily headache diary for 16 weeks an recorded frequency and intensity of pain.	[use of over the counter medication, pills/day, mean(SD)] 4 weeks post treatment	**Group 2** n=47 Baseline: 1.8 (1.2) Final: 1.3 (1.3) **Group 3** n= 54 Baseline: 2.0 (1.5) Final: 1.7 (1.5)	

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

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Tuchin et al, 2000[806] **Study design:** RCT **Comparison:** Spinal manipulation v Control **Setting:** Chiropractic research Centre of Macquarie University, Australia **Duration of follow-up:** 6 months	**Patient group**: Adults with a diagnosis of migraine **Inclusion criteria:** Aged 18-70 years; minimum of five of the following indicators: inability to continue normal activities or need to seek a quiet dark area, pain located around temples, pain described as throbbing, associated with nausea, vomiting, aura, photophobia, migraine precipitated by weather changes, migraine aggravated by head or neck movements, previous diagnosis of migraine by a specialist, family history of migraine; minimum of one migraine a month. **Exclusion criteria:** Participants experiencing daily migraine, with the initiating factor being trauma; contraindications to spinal manipulative therapy; presence of temporal arteritis, benign intracranial hypertension or space occupying lesions. **All patients** **N:** 127 **Age in years (mean):** NR **Drop outs:** 4 (1-alteration in work situation, 1-fractured ankle, 1-	**Group 1 Chiropractic spinal manipulative therapy (CSMT)** Group received two months of CSMT treatment consisting of chiropractic diversified technique at vertebral fixations determined by the practitioner. The level of spine manipulated was not specified. *CSMT is defined as a passive manual manoeuvre during which the 3-joint complex is carried beyond the normal physiologic range of movement without exceeding the boundaries of anatomic integrity. **Group 2 Control** Detuned interferential therapy consisting of electrodes being placed on the patient with no current sent through the machine. Trial consisted of three stages: 2 months of data	**Patient-reported headache frequency** [average number of migraines per month, mean(SD)]	**Group 1:** Baseline: 7.1(6.98) After treatment: 4.1 (6.55) **Group 2:** Baseline:7.3(6.53) After treatment: 6.9(6.6) **p value:** <0.005	**Funding:** NR **Limitations:** Unclear randomization and allocation concealment. Unclear if comparable at baseline. Inclusion criteria states and age range of 18-70 years, but age ranges for both groups reported elsewhere in the study include children.* **Additional outcomes:** Hours before return to normal for an average episode Duration/hours for an average episode **Notes:** Patient blinding was achieved by participants being informed that they may be randomly assigned to a control group that would receive a placebo. *Age ranges include children (confirmed by study author).
			Patient-reported intensity [100 mm VAS for average episode, mean(SD)]	**Group1:** Baseline:7.96 (1.4) After treatment: 6.9 (1.8) **Group 2:** Baseline: 7.89 (1.2) After treatment: 6.2 (1.7) **p value:** NS	
			Use of acute pharmacological treatment[average number of medications per month, mean(SD)]	**Group1:** Baseline:21.3(28.4) After treatment: 9.8 (12.4) **Group 2:** Baseline: 20.1(28.4) After treatment: 16.2(12.4) **p value:** <0.001	

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	soreness after CSMT, 1-increase in migraine after CSMT) **Group 1 –** Chiropractic spinal manipulative therapy (CSMT) **N:** 83 **Age in years (mean):** 39.6(range 10-70) **Drop outs:** NR **Group 2 -** Control **N:** 40 **Age (mean):** 37.8 (range 17-66) **Drop outs:** NR	collection prior to treatment, 2 month treatment phase and 2 months follow up phase. Participants completed diaries for the 6 months of the study			

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, CSMT = Chiropractic spinal manipulative therapy, VAS=Visual Analogue Scale, NS=Not significant, IHS=International Headache Society