Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Abram et al, 2007[5] **Study design:** RCT **Comparison:** Headache clinical model vs traditional clinical model **Setting:** Primary care or outpatient clinic **Duration of follow-up:** 3 months And 6 months	**Patient group:** Children and adolescents, 10-18 years. **Inclusion criteria:** Referred by primary care physician or self referred for neurological consultation at a paediatric outpatient multi-speciality clinic. Minimum of 2 month history of recurrent primary headache disorder (migraine, TTH, mixed or chronic daily). **Exclusion criteria**: Past formal neurological or psychological consultation or a known significant abnormality on a neuroimaging or neurological examination. <u>All patients</u> **N:** 81 **Age (mean):** 12.7 **Group 1 – Headache clinic** **N:** 41 **Age (mean):** 13.3 **Drop outs:** 16 **Male (%):** 44 **White (%):** 83 **Time from referral to initial visit (days):** 17 **Headache diagnosis (%):**	**Group 1 - Headache clinical model (HCM)** Small group appointment, 4-6 patients and their parents attended a 1 hour educational session. Included education about headache, education about role of stress in headache, potential treatments were introduced, concluded with a guided practice in deep breathing, progressive muscular relaxation and imagery. This was followed immediately by an individual consultation with a child neurologist **Group 2 –Traditional clinical model (TCM)** Individual consultation with a paediatric neurologist	**Headache specific Quality of life (QoL) pedMIDAS** Outcome data available for 50 patients at 3 months, and for 66 patients at 6 month visit	**Baseline** **Group 1:** 59 **Group 2:** 43 **p value:** 0.086 **3 months** **Group1:** -40% **Group 2:** -50% **p value:** 0.24 between groups **Baseline to 3 months p=**0.000 NS from 3 to 6 months p=0.297	**Funding:** Nemours clinical management programme, Orlando. **Limitations:** Blinding unclear, not stated whether participants or their parents knew aim of study, or which was considered the experimental treatment group. pedMIDAS n for individual groups not stated. Limited reporting of values for pedMIDAS. **Notes:** Randomised using a random number table.
			Headache specific QoL Functional Disability Inventory (FDI) parent No group or group x time effects	**Baseline** **Group 1:** 18 **Group 2:** 20 **p value:** 0.453 **3 months** **p value: 0.004** <u>6 months</u> p value: 0.00	
			Headache specific QoL FDI child No group or group x time effects	**Baseline** **Group 1:** 18.41 **Group 2:** 18.6 **p value:** 0.95 **3 months** **p value:** 0.075 <u>6 months</u> p value: 0.002	
			Resource use **Psychological**	**3 months** **Group1:** 14.6%	

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	Migraine: 20, Episodic tension type headache: 7, Mixed: 59, chronic daily: 15 **Group 2 – Traditional clinic** **N:** 40 **Age (mean):** 12.1 **Drop outs:**15 **Pharm treatment:** NR **Male (%):** 45 **White (%):** 90 **Time from referral to initial visit (days):** 17 **Headache diagnosis (%)** Migraine: 43, Episodic tension type headache: 7, Mixed: 35 - chronic daily: 15		**treatment** % use	**Group 2:** 7.5% **p value:** 0.271 6 months Group1: 9.1 Group 2: 3.0 p value: 0.302	
			Resource use **Calls to neurology clinic** % use	**3 months** **Group1:** 19.1 **Group 2:** 11.5 **p value:** 0.15 6 months Group1: 9.1 Group 2: 3.0 p value: 0.80	
			Resource use **Emergency department visits** % use	**3 months** **Group1:** 7.7 **Group 2:** 7.6 **p value:** 0.70 6 months Group1: 0 Group 2: 6.1 p value: 0.16	

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, pedMIDAS= Paediatric Migraine Disability Assessment, FDI= Functional Disability Inventory, TTH=tension type headache

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Kohlenberg & Cahn 1981[446] **Study design:** RCT **Comparison:** Instructions on self management vs control **Setting:** NR **Duration of follow-up:** 6 weeks baseline, Followed up at 22 weeks (3 months after finishing the book)- 4 weeks of headache data was collected, then 6 month follow up where an additional 4 weeks of data were collected	**Patient group:** Patients with a diagnosis of migraine **Inclusion criteria:** At least 2 headaches per month, diagnosed as having migraine headaches by their doctor and currently be under his or her care, be willing to collect data on headaches on a daily basis, be willing to collect data for 6 weeks prior to receiving any experimental treatment. Physician to document all of the above in writing. **Exclusion criteria:** Severe psychiatric problems, high or low blood pressure, subject to strokes. **All patients** **N:** 117 **Drop outs:** 66 **Group 1 – experimental book** **N:** 58 **Age (mean):** 44.0 **Drop outs:** 36 **Number of years suffering from migraine:** 19.9	**Group 1- Experimental book** Included a liquid crystal finger temperature band. Contains 7 chapters, includes information on: physiological basis of migraine; importance of avoiding vasoconstriction; how to use the temperature device as biofeedback instrument; relaxation exercise (meditation and progressive relaxation); biofeedback exercise; and cognitive restructuring. **Group 2 –Control book** "More than 2 aspirin" (S. Diamond & W. B. Furlong) Series of case histories, question and answer session. Primary purpose of book is to provide information about symptoms, diagnosis and treatment of headaches. **Both groups** Participants told in the consent form that two different books were being	**Change in patient-reported headache frequency** % decrease figures only stated	**Group1:** 62% **Group 2:** 14% **p value:** NR F (2,94) = 6.9 (period interaction) Differences between baseline and 3 & 6 months significant within and between groups	**Funding:** NR **Limitations:** Study does not state blinding status, although appears that subjects were blind, unclear about investigartors. Patient demographics only on the 51 that completed the study. Change in patient reported headache frequency (number of headaches) only given as % decrease. Large number of dropouts (treatment 62%; control 51%), study reports this may be to do with lack of contact through study. Only 1 male participant completed the study. Partial reporting of change in headache intensity. **Additional outcomes:** Confidence ratings before and after (0-5 scale). Headache duration. **Notes:** Patients were recruited through advertisements in local
			Change in patient-reported headache intensity (headache pain) Recorded on a 0 (no pain)-5 (worst pain ever) scale	**Group1:** F(2,92) = 52 (treatment group statistically greater pain reduction than control) **Group 2:** NR Both groups significantly reduced pain ratings from the baseline period F(1,92) = 5.7	
			Use of acute pharmacological treatment Mean number of doses (tablet, capsules etc) per week	**Baseline:** **Group1:** 6.6 **Group 2:** 2.8 **3 month** **Group1:** 4.1 **Group 2:** 2.2 **6 month** **Group1:** 2.9 **Group 2:** 2.2	
			Confidence rating	**Baseline:**	

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	Group 2 – control book **N:** 59 **Age (mean):** 46.7 **Drop outs:** 30 **Number of years suffering from migraine:** 20.1	tested. People given 10 weeks to finish the book, contacted at 22 weeks after receiving the book (or 3 months after finishing the book).	(Patients perception of the usefulness of programmes)	**Group1:** 2.8 **Group 2:** 3.8 **After reading book** **Group1:** 2.6 **Group 2:** 3.5	newspapers, public service announcements on the radio asking for volunteers. Patients had to pay $25 deposit to participate in the study which they received upon completion of the study or if they withdrew. Only contact with patients was by mail or phone. Statistical tests- 3 ways analyses of variance with repeated measures- F significance. Individual mean comparisons with Scheffe test.

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: Larsson et al, 1987[476] **Study design:** RCT **Comparison**: Therapist-assisted relaxation vs self help relaxation vs control **Setting:** High schools in Sweden **Duration of follow-up:** 5 months	**Patient group:** Adolescents aged 16-18 years, suffering from migraine, migraine and tension type headache or non-migrainous headache. **Inclusion criteria:** Headache complaints for at least once a week, having headaches for at least 1 year, not receiving psychological or pharmacological treatment for their headaches at the present time. **Exclusion criteria: NR** **All patients** **N:** 46 **Age (mean):** NR for any group **Drop outs**: 5 **Group 1 – Self help relaxation** **N:** 16 **Drop outs:** 2 **F/M:** 11/5 **Headache type:** Migraine: 1, Mixed: 2, Tension: 13 **Headache duration (years):** 1-5: 11, >5: 5 **Depression/ anxiety range 35-120 [mean, SD]:** 56 (10.7) **Stress, range 11-44 [mean, SD]:** 23.5	**Group 1 –Self-help relaxation** A series of 5 audiotapes roughly 5-10 minutes duration, developed by the experimenters. Same type of relaxation instructions as used by group 2. Treatment introduced by school nurse at initial meeting. Students urged to change the tapes once a week. Nurses contact 2 months after initial intervention to give participants a booster tape which contained instructions to practise critical steps in relaxation treatment. **Group 2 – Therapist assisted relaxation (TAR)** 9 x 45 minute sessions, twice a week during regular school hours. Sessions 1-3: Progressive relaxation training conducted in groups of 3-4 students. Session 4: rapid "cue controlled" relaxation technique was introduced. Final 2-3 sessions: practise of "cue controlled" technique and extended it to everyday	**Change in patient-reported headache days** **"Headache free days"**	**Baseline** **Group 1:** 1.8 **Group 2:** 2.1 **Group 3**: 1.4 **5 months follow up** **Group 1:** 3.6 **Group 2:** 4.9 **Group 3:** 1.7 **p value:** **Group 1:** <0.001 **Group 2:** <0.01 **Group 3:**NS	**Funding:** NR **Limitations:** Does not state what time period pre-follow up is. Restrictions applied to randomisation: classmates were assigned to the same treatment group in order to reduce the risk of contamination; subjects were evenly distributed across groups within separate schools. No allocation concealment- active selection bias. Binding not stated, appears to be open label. Not clear what scale confidence rating is assessed on. **Additional outcomes:** Headache duration. Headache sum.
			Change in patient-reported headache frequency	**Baseline** **Group 1:** 5.8 **Group 2:** 5.1 **Group 3:** 5.7 **5 months follow up** **Group 1:** 3.5 **Group 2:** 2.3 **Group 3:** 5.5 **p value:** **Group 1:** <0.001 **Group 2**: <0.001 **Group 3:**NS	
			Change in patient-reported headache intensity **Peak headache intensity**	**Baseline** **Group 1:** 3.3 **Group 2:** 3.2 **Group 3:** 3.6 **5 months follow up**	

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
	(5.5) **Group 2 – Therapist assisted relaxation** **N:** 14 **Drop outs:** 2 **Female/ male:** 13/1 **Headache type:** Migraine: 1, Mixed: 4, Tension: 9 **Headache duration (years):** 1-5: 10, >5: 4 **Depression/ anxiety, range 35-120 [mean, SD]:** 58.6 (13.3) **Stress, range 11-44 [mean, SD**]: 22.3 (5.0) **Group 3 – Self- monitoring** **N:** 11 **Drop outs:** 1 **Female/ male:** 11/0 **Headache type:** Migraine: 0, Mixed: 4, Tension: 7 **Headache duration (years):** 1-5: 5, >5: 6 **Depression/ anxiety, range 35-120 [mean, SD]:** 55.5 (6.2) **Stress, range 11-44 [mean, SD]:** 22.31 (4.4)	situation. Two booster sessions at 2 months following initial treatment. **Group 3 – Self monitoring** Perform self- recordings and did not receive any treatment. Informed of group membership by telephone by the child psychiatrist and encouraged to seek help at regular school health services in case they experienced deteriorating headache.		**Group 1:** 2.3 **Group 2:** 2.5 **Group 3:** 3.1 **p value:** **Group 1:** <0.01 **Group 2:** NS **Group 3:** NS	School absence. Cost effectiveness. Treatment compliance. **Notes:** Recorded headache activity on a 6-point scale (0=no headache to 5= tense incapacitating headache). Lottery used throughout the study in which participants had opportunity to win ~£2 each week after they had handed in their report card to the nurse. Groups equivalent at baseline.
			Responder rate (50% reduction in headache complaints) Outcome measured at - "pre-follow up"	**Pre-follow up** **Group 1:** 1/16 (8%) **Group 2:** 1/14 (9%) **Group 3:** 0/11 (0%) **p value: <**0.01	
			Use of acute pharmacological treatment	Stated as outcome but not reported	
			Confidence rating Students experience of how effectively headaches were reduced (Likert scale 1=very little, 5=very much and 1=not helpful to5= very helpful) Or Four 10 point scales (1=not at all, 10 very much) Mean (SD)	**Group 1:** 3.9 (0.5) **Group 2:** 4.1 (0.6) **Group 3:** NR	

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, TAR=therapist assisted relaxation

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Lemstra et al, 2002[486] **Study design:** RCT **Comparison:** **Setting:** YMCA centre **Duration of follow-up:** At 6 weeks and 3 months	**Patient group:** Adults with migraine with or without aura according to IHS. **Inclusion criteria:** Patients 18 years of age or older with a chronic migraine pain for at least 6 months, meet the diagnostic criteria for migraine with or without aura according to IHS. **Exclusion criteria**: If pain was of a benign nature. **All patients** **N:** 80 **Drop outs:** 3 **Group 1 – 6 week intervention** **N:** 44 **Age (mean):** 35.59 (10.15) **Drop outs:** 3 **Gender (f/m):** 32 (72.7%)/12 (27.3%) **Education:** University or college: 16/44, High school graduate: 25/44, Less than high school graduation: 3/44 **Current self-reported health (1-5):** 3.60 (1.03) **Onset of pain (months):** 102.91 (77.75) **Days in last month with pain:** 20.20 (8.07) **Number of non prescription**	**Group 1 – 6 week intervention** (neurologist intake, physical therapist intake, 18 group supervised exercise classes with exercise therapist, 2 group lectures with a psychologist, 1 group lecture with a dietician, 2 massage therapy session, neurologist and physical therapist discharge) submaximal general exercise, education, lifestyle changes, and self-management Active participation maximised with supervised visits, telephone calls with every absence and scheduled attempts to try and to determine knowledge retention. Development of a coordinated management plan for the patient. **Group 2- waiting list control** was standard medical care with patient's family physician, control intervention was referral to medical specialist (19%), referral to treatment (11%), medication (56%), further	**Change in patient-reported headache frequency** Visual analogue scale: 100% worse to 100% improvement After intervention measurements only	**Group1:** 56.93 (9.13) **Group 2:** -2.22 (2.22) **p value:** 0.000	**Funding:** NR **Limitations:** Study not blinded. All outcomes are patient perceived change- therefore subjective. Headache frequency measured differently to other studies. Outcomes for headache frequency intensity. Functional health status health-related quality of life only reported for end of intervention, not at baseline. **Additional outcomes:** Change in pain duration. Change in average pain. Change in most pain. Change in least pain. Change in hours of pain. Change in pain disability index. Change in beck depression inventory. Change in work status (%). **Notes:** Randomisation: individual computer generated, envelope concealed under the
			Change in patient-reported headache intensity Visual analogue scale: 100% worse to 100% improvement After intervention measurements only	**Group1:** 38.18 (8.54) **Group 2:** -2.78 (1.98) **p value:** 0.001	
			Functional health status 1 (excellent health) – 5 (poor health) After intervention measurements only	**Group1:** 51.59 (7.71) **Group 2:** -0.56 (2.03) **p value:** 0.000	
			Health-related quality of life Visual analogue scale: 100% worse to 100% improvement After intervention measurements only	**Group1:** 57.05 (8.17) **Group 2:** -1.94 (1.94) **p value:** 0.000	
			Use of acute	**Group1:** 1.06 (0.22)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	medications: 1.86 (0.95) **Number of prescription medications:** 2.55 (2.17) **Expect intervention will help (%):** 12/44 (27.3) **Group 2 - Control** **N:** 36 **Age (mean):** 33.17 (13.21) **Drop outs:** 0 **Gender (f/m %):** 21(58.3%)/15(41.7%) **Education:** University or college: **12/36**, High school graduate: **23/36,** Less than high school graduation: **1/36** **Current self-reported health (1-5):** 3.67 (0.89) **Onset of pain (months):** 101.67 (128.35) **Days in last month with pain:** 21.08 (8.33) **Number of non prescription medications:** 2.0 (0.89) Number of prescription medications: 2.17 (2.09) **Expect intervention will help (%):** 13/36 (36.1)	diagnostics (0%), education (0%), nothing at all (14%)	**pharmacological treatment** non prescription drug use in the last 30 days *Before and after measurements*	**Group 2:** 0.25 (0.12) **p value:** 0.005	supervision of the data manager. Blinding of patients not considered possible, treatment credibility assessed in patients and therapists before intervention. Therapists blinded to which specific outcome variables were primarily under evaluation. Outcome assessor blinded to intervention status. ITT analysis.
			Use of acute pharmacological treatment Prescription drug use in the last 30 days *Before and after measurements*	**Group1**: 1.18 (0.24) **Group 2:** 0.22 (0.11) **p value:** 0.001	

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: Williamson & Reeder, 1984[852] **Study design:** RCT, 3 x 3 factorial design **Comparison:** Group relaxation vs self help vs waiting list control **Setting:** **Duration of follow-up:** 4 months (see notes and limitations*)	**Patient group:** Self-referred patients recruited by media advertisement with migraine, muscle contraction or mixed headache. **Inclusion criteria**: Diagnostic interviews indicated that the patient met the criteria to be diagnosed as either classic migraine, common migraine, muscle contraction or mixed headache, reported at least 3 headaches during a month of baseline recording, they did not report experiencing head pain every day, they agreed to complete all stages of the study and their personal physician agreed to allow them to participate in the experiment. **Exclusion criteria:** Not meeting diagnostic criteria or presented symptoms of other potential causes of head pain. **All patients** **N:** 48 **Drop outs:** 7 **Group 1 - self help relaxation**	**Group 1 self help relaxation** Divided into 3 groups; each led by one of three pairs of therapist. Met once per week for approximately 1 hour for 4 weeks. Received copies of the relaxation book (Rosen 1977) and given instructions how to use the self help guide. Purpose of sessions to promote compliance with self monitoring procedure and the relaxation programme. **Group 2 group relaxation training** Divided into 3 groups; Sessions twice a week for four weeks. Sessions lasted approximately 1.5 hours. Trained in progressive muscular relaxation using 16 muscle group relaxation. Actual practise of the technique and discussion. Provided with audiotapes of the relaxation procedure and instructed to use the tapes at least once daily. Taught abbreviated relaxation procedure and provided with tapes. Identifying stress and headaches and use of relaxation to cope with this. Practise of relaxation by recall. **Group 3 waiting list control** Met for 4x 1 hour sessions over 4 weeks to discuss physiological and psychological basis of headache. **All patients** Self monitored headache activity for 3 (or 4) weeks.	**Change in patient-reported headache frequency** **Responder rate** Greater than or equal to 50% reduction of headache activity from baseline to follow up	**F** (2, 102) = 0.55 **p value:** >0.10 **Group 1**: 5/14 (35.7%) **Group 2:** 4/13 (30.8%) **Group 3:** 1/14 (7.1%) **p value:** NR	**Funding:** NR **Limitations:** Allocation concealment and blinding NR (assumed open label). Values for change in patient-reported headache frequency not given. Outcomes are for 1 month only. Additional analyses at 2, 3, 4 months not performed as headache data for control group not available. **Additional outcomes:** Change in headache index. Response of individuals to treatment conditions (% improvement). **Notes:** Available case analyses. Initially designed as a 3x3 factorial.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 16 **Age (mean):** 39.1 **Drop outs:**2 **Male/ female:** 4/12 **Group 2 – group relaxation training** **N:** 16 **Age (mean):** 37.6 **Drop outs:** 3 **Male/ female:** 1/15 **Group 3 – waiting list control** **N:** 16 **Age (mean):** 39.5 **Drop outs:** 2 **Male/ female:** 4/12				

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