

There is good evidence (Level 1a) to support the use of relaxation therapy for children and adolescents with headaches.

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CLINICAL SCENARIO:

Children and adolescents with recurrent headache are frequently referred to occupational therapy for relaxation therapy. We wanted to investigate the research evidence to determine whether continuing to provide relaxation therapy to these children and adolescents was justified.

FOCUSSED CLINICAL QUESTION:

What is the evidence that relaxation therapy decreases symptoms of paediatric headache?

SUMMARY of Search, 'Best' Evidence Appraised, and Key Findings:

- 1 Cochrane Systematic Review (Eccelston et al 2003) was located. This review concluded that relaxation was effective in reducing pain in children with headache. Eccleston reviewed studies up to the end of 1999.
- The literature was then searched for RCTs published from 1999 to August 2005.
- This search retrieved another RCT (Fichtel & Larsson, 2001; PEDro score = 4/10) which investigated the effects of relaxation on migraine and on tension-type headache (TTH). It concluded that relaxation was effective in reducing total headache and migraine intensity and frequency, but did not influence TTH.

CLINICAL BOTTOM LINE:

On the basis of the systematic review and the RCT it can be concluded that there is sufficient evidence to support the continuing use of relaxation therapy for the management of paediatric and adolescent headache by occupational therapists and others.

Limitation of this CAT: This critically appraised paper has not been externally peer-reviewed.

SEARCH STRATEGY:

Terms used to guide Search Strategy:

- **P**atient/Client: headache OR migraine
- **I**ntervention: relaxation OR meditation OR visualisation OR hypnosis OR imagery
- **C**omparison: Nil
- **O**utcome(s): Nil
- **L**imits: children/adolescents; research (systematic reviews, RCTs)

Sources of evidence searched

Cochrane Library

PEDro

OTseeker

CINAHL

Medline

Embase

PsychINFO

INCLUSION and EXCLUSION CRITERIA

- **Inclusion:**
Clinic based studies that evaluated headache/migraine outcomes of relaxation therapy for children and adolescents.

RESULTS OF SEARCHES

Two relevant studies were located and categorised as shown in Table 1 (based on Levels of Evidence, Centre for Evidence Based Medicine, 1998)

Table 1: Summary of Study Designs of Articles retrieved

Level of Evidence	Study Design/ Methodology of Articles Retrieved	Number Located	Source(s)
Ia	Systematic Review	1	Cochrane Library
Ib	RCT	1	Embase and Medline

Two other recent articles were located but not included in this CAT as they did not meet the inclusion criteria i.e. they related to school, not clinic, based intervention. These were:

Larsson, B., Carlsson, J., Fichter, A., & Melin, L. (2005). Relaxation treatment of adolescent headache sufferers: Results from a school-based replication series. *Headache*, 45, 692-704.

Fichtel, A., & Larsson, B. (2004). Relaxation treatment administered by school nurses to adolescents with recurrent headaches. *Headache*, 44, 545-554.

BEST EVIDENCE

The two located articles were identified as the 'best' evidence as:

- i) The Eccleston Systematic Review (2002) is sound Level I evidence but contained RCTS published only to 1999.
- ii) The RCT by Fichtel and Larsson (2001) was the only systematic review or RCT published from 1999 to 2005 and eligible for inclusion.

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of systematic review by Eccleston et al., 2002

Aim of the Systematic Review

Assess effectiveness of psychological therapies in treating chronic or recurrent pain in children and adolescents.

Method

Eligible studies:

RCTs, with at least 5 participants in each study arm

Participants:

People younger than 21 years with recurrent or chronic pain, from any cause, of at least 3 months duration, from a clinical or outpatient population

Intervention:

Psychological therapies (eg relaxation, biofeedback, behaviour therapy, cognitive behaviour therapy, hypnosis etc) compared with placebo, waiting list or standard medical care

Outcome Measures:

Analyses of a number of outcomes (eg affect, social role performance, quality of life) were planned but the only outcome which had analysable data was pain. Each included trial used a version of the same commonly used pain diary derived from the work of Budzynski (1973). For each study, a Pain Index was derived, commonly from the summation of pain intensity ratings. The Pain Index captures the total amount of pain experience. Pain Index is reported as the percentage of change from baseline. Fifty percent reduction in Pain Index was deemed clinically significant. The data analysed in this review then, were dichotomous data (ie odds ratio of those who did versus those who did not achieve a 50% reduction in pain from baseline).

Search:

The Cochrane, Medline, PsycLit, EMBASE and Social Sciences Citation Index databases were searched from their inception to the end of 1999. Reference lists were searched and experts contacted. CINAHL however was not searched, nor was

handsearching of journals completed. Search terms focused on pain, causes of pain such as headache, migraine, stomach/abdominal pain etc and a small range of terms for psychological therapies. Terms related to relaxation therapy were not used in the search strategy.

Eligible studies were determined and data extraction completed by four reviewers independently. Methodological quality of the studies was clearly discussed.

Results

- 28 RCTs were retrieved, of which 18 were eligible for inclusion and 13 of these provided Pain Index data suitable for meta-analysis. Overall the meta-analysis reported an odds ratio of 8.83 (95%CI 1.33-18.03) or 8.64 (95%CI 4.13-18.07), depending on the analysis completed. Odds ratios are not intuitive to interpret so the Numbers Needed to Treat (NNT) was calculated. The NNT was 2 meaning that for every 2 people treated, on average one will benefit from the treatment.
- This systematic review did not meta-analyse the trials examining relaxation as an intervention separately from other interventions. However, 11 of the 18 trials used relaxation to treat headaches, and of these 7 had pain index data to meta-analyse. The odds ratios reported separately for these studies ranged from 4.5 to 27.5 with large 95% CIs. This indicates treatment efficacy across the range of studies.

Original Authors' Conclusions

There is good evidence that psychological treatments, principally relaxation and cognitive behavioural therapy are effective in reducing the severity and frequency of chronic headache in children and adolescents. There was no evidence that psychological therapies were effective in attenuating pain in conditions other than headache or for outcomes other than pain.

Critical Appraisal of Systematic Review by Eccleston et al., (2002):

This systematic review had the clearly stated, but broad aim, of examining psychological therapies used by children with pain. This aim was broader than our question regarding the impact of relaxation on headache. However, the results of the meta-analysis were contributed to largely by studies addressing relaxation and headache (ie 7 of the 13 meta-analysable studies).

Strengths:

Generally the systematic review was carried out in a valid and objective and well reported manner.

As is usual for Cochrane reviews, more than one reviewer appraised and extracted data from each article.

The methodological quality of the studies was examined.

The outcome (pain index) itself incorporated clinically significant change.

Weaknesses

The search was weakened predominantly by failing to search CINAHL and failing to use specific terms related to relaxation.

The search was completed only to 1999.

Pain was the only outcome able to be meta-analysed, there are many other important outcomes of interest and relevance (eg: functional ability, coping, quality of life etc).

The nature of relaxation interventions was not identifiable from the review. The original trials, therefore, will need to be consulted to identify the specific techniques used in the studies that demonstrated the effectiveness of relaxation.

Results

Examining the odds ratios for the individual relevant studies indicates that the conclusions drawn by the systematic review authors are valid. That is, the authors' conclusion that relaxation is effective in managing paediatric headache is valid.

Table 3: Description and appraisal of RCT by Fichtel & Larsson (2001)

Aim of the Study

- To determine whether relaxation was more effective than a waiting list control in reducing headache frequency, intensity, duration and medicine consumption, and increasing headache-free days in adolescents with headache.
- To determine whether relaxation influenced migraine and tension-type headaches (TTH) differently
- To determine whether any effects were maintained for 8 to 12 months.

Sample: 36 adolescents (age 13-18 years, mean=14.5) were recruited by inviting students from 2 high schools in Sweden (n=28) and by a newspaper advertisement (n=8). Five participants had migraine only, 31 had migraine and TTH. Inclusion criteria included frequent migraine for at least 6 months; fulfillment of the International Headache Society diagnostic criteria for migraine or both migraine and TTH; and to experience migraines at least twice per month. Participants with secondary headache (eg due to physical or mental disease) were excluded.

Method: Participants were randomly assigned to relaxation (n=20) or waiting list control (n=16) groups (randomization not described). Headaches diaries were kept prior to intervention, the intervention was completed and then the headache diaries completed again.

Intervention: 8 to 10 sessions, of 45-minutes duration, were given in groups at schools or individually in clinics for those participants recruited via newspaper ads. There were no differences in outcomes for the group vs individual interventions. Psychologists carried out the treatment. The sessions covered: information and rationale behind treatment, several different forms of relaxation, how to apply techniques in everyday situations and how to maintain skills.

Outcome Measures

Headache diaries were used to record headache activity and type of activity (eg migraine or TTH) 4 times per day. It is not clear but it seems that the diary was kept for 4 weeks prior to and 4 weeks following intervention and again 8 to 12 months after intervention. The following information was extracted for migraines, TTH and total headache, and used as outcome measures:

- Headache intensity – headache intensity was rated 4 times daily on a 6-point Likert scale. Headache intensity was then reported as the sum of weekly scores: total range 0-140.
- Headache frequency – number of headaches per week, range = 0-14

- Headache free days
- Headache duration – 1 unit = 5 hours
- Peak headache intensity – scale 0-6.
- Medication use

Clinically meaningful improvement was estimated as 50% reduction in headache activity between pre-assessment and post-assessment.

Results

Only statistically significant results** presented here (ie $p < 0.05$):

Outcome	Improvement (change from baseline to time 2)		Range of scores
	Relaxation group	Control group	
Total headache intensity	8.3	1.9	0-140
Total migraine intensity	5.3	2.16	0-140
Migraine frequency	.78	.33	0-14
Peak total intensity	.92	-.08	Unknown
Peak migraine intensity	.092	.65	Unknown

** Precise p-values not given in original report.

Total headache and migraine intensity, peak total intensity, and migraine intensity increased; and migraine frequency decreased statistically in the relaxation group. The magnitude of the change however was not great. There was no difference in any TTH behaviour between groups, nor in headache-free days, duration of headaches or medicine consumption.

Fifty percent of the relaxation group achieved a clinically meaningful (ie 50% reduction) in total headache activity compared with 12% in control group; this was a statistically significant difference. There was no statistically significant difference between groups in terms of proportion achieving a clinically meaningful change for migraine activity (68% of relaxation group vs 38% of control group) or for TTH (42% of relaxation group vs 40% of control group).

Authors' conclusion: Total headache activity was significantly reduced after relaxation compared with the control group. Migraine was significantly improved but TTH did not improve more in the relaxation group than the control group.

Critical Appraisal

Validity (Methodology, rigour, selection, bias) PEDro SCORE = 4/10 (points allocated for random allocation, adequacy of follow-up, between group comparisons and reporting of point estimates and variability).

- Randomization not described
- Length of time headache diary was maintained is not clear nor is how long the intervention spanned.

- Meaningful information was not provided for the 8-12 month follow up evaluation of 20 participants.
- Multiple comparisons were carried out thus increasing likelihood of finding significant results. No adjustments were made to p-values for these multiple comparisons, nor were precise p-values provided.
- Baseline equivalency is not clear. No statistical analysis of differences between groups at baseline on key outcome measures (such as headache intensity and frequency) was provided. No report or comparison of demographic characteristics between groups was given.

Results

The relaxation group appeared to make small gains in total headache intensity and migraine intensity compared to the control group.

IMPLICATIONS FOR PRACTICE

Occupational therapists tend to provide relaxation therapy, along with education regarding how to apply stress management and relaxation in daily life, in both groups and on an individual basis. There are no particular clinical guidelines to follow so an important next step is to appraise the specific techniques employed in the existing rigorous trials to attempt to develop effective and generalisable clinical guidelines.

The outcome measures used by Fichtel and Larsson (2001) are universally accepted measures of headache-specific activity. Occupational therapists may also consider client-focussed outcomes that are important to individuals using measures such as the Canadian Occupational Performance Measure and Goal Attainment Scaling.

Future research should investigate the effects of specific relaxation techniques, delivery modes, frequency etc, and effect of clinical guidelines for the use of relaxation therapy for paediatric headache

REFERENCES

Articles critically appraised:

Eccelston, C., Yorke L., Morley, S., Williams, A.C. de C., & Mastroiannopoulou, K. (2003). Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *The Cochrane Database of Systematic Reviews*, Issue 1.

Fichtel, A., & Larsson, B. (2001). Does relaxation treatment have differential effects on migraine and tension-type headache in adolescents? *Headache*, 41, 290-296.

Other references:

Budzynski, T.H., Stoyva, J.M., Adler, C.S., & Mullaney, D.J. (1973). EMG biofeedback and tension headache: A controlled outcome study. *Psychosomatic Medicine*, 35(6), 484-496.