Psychological treatment of recurrent headache in children and adolescents: a meta-analysis

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CRD summary
The authors concluded that efficacy of psychological treatments in paediatric headache patients is supported at evidence level 1a (several consistent RCTs support efficacy). Treatment efficacy is demonstrated for up to 1 year and shows a trend for further improvement beyond this point. Given the unclear quality of included studies and the potential for reviewer error and bias, the authors’ conclusions should be treated with caution.

Authors' objectives
To evaluate the effectiveness of psychological treatments for headaches in children and adolescents.

Searching
MEDLINE, PsycINFO, PSYNDEX and the Cochrane Library were searched from inception to July 2004 for articles in English or German. Search terms were reported. Additional searches were carried out in reviews, previous meta-analyses and on the Internet. Researchers were contacted in order to identify unpublished material.

Study selection
Randomised controlled trials (RCTs) of relaxation training, biofeedback or cognitive behavioural therapy (CBT) administered singularly or in combination as treatment for migraine or tension-type headaches in children or adolescents were eligible for inclusion. Participants had to experience two or more headache attacks per month. Inclusion criteria for control groups were waiting list or active control consisting of non-specific treatment factors. Inclusion criteria for study design were RCTs or trials in which randomisation occurred after groups were matched. Trials were required to have a minimum of four participants each in the treatment and control groups to be eligible for inclusion. Sufficient had to be reported to enable calculation of the effect size. Outcomes eligible for inclusion were frequency, intensity and/or duration of headaches.

Included interventions were: CBT (home or clinic based, group or individual); biofeedback (EMG (electromyography), EEG (electroencephalogram), hand warming or hand cooling); differing forms of relaxation treatment (autogenic, relaxation response, progressive muscular relaxation); cephalic vasomotor training; and stress management. Some interventions were school based. Duration of treatment ranged from 2 to 12 sessions. Where stated, the average age of participants was 9 to 15 years (range 7 to 22 years) and the majority of participants were female. As well as the main outcomes of interest, use of medication was explored. Follow-up ranged from 4 to 12 months. Two studies did not have a follow-up period. Included trials were conducted in the USA, Canada, Australia, Germany, Sweden and the Netherlands.

The authors did not state how the studies were selected for the review or how many reviewers performed the study selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Data were extracted by two authors. It appeared that this was carried out independently; however, it was not explicitly stated. The number of participants whose headache symptoms reduced by 50% or more was extracted to give a measure of clinically significant change for each study. Means, standard deviations (SD) or probability levels for each outcome were extracted to enable calculation of effect sizes for individual studies using Hedges’ g. Where more than one measure was used for an outcome, the effect size was calculated by averaging the effect sizes.

Methods of synthesis
Results were combined in a meta analysis using both random-effects model (REM) and fixed-effect model (FEM).
Both between group and within group effects were calculated. Individual studies were weighted using the reciprocal of the variance components. Statistical heterogeneity was investigated using the Q statistic. The trim and fill method was applied to correct for any possible publication bias. Sensitivity analysis was carried out excluding school-based interventions. Subgroup analyses were carried out investigating the differential effects of types of intervention and types of headache.

**Results of the review**

Twenty three trials were included in the review (n=999); 18 RCTs and five controlled trials with randomisation after matching procedures. Drop-outs ranged from 0% to 65%.

**Between Groups analyses:**

Psychological treatment was associated with a small effect on overall headache variables (10 trials, REM: g=0.35, 95% CI: 0.08, 0.61), but a significant moderate benefit on headache intensity (nine trials, REM: g=0.43, 95% CI: 0.11, 0.74) compared to waiting list controls. Medication use was not affected by treatment (five trials). Sensitivity analysis excluding the school based interventions did not alter the results. Significantly more people in the psychological treatment group showed clinically significant reduction in symptoms (16 trials, REM: g=0.87, 95% CI: 0.57, 1.16) compared to waiting list controls. There were no significant differences between psychological treatment and active control groups on headache variables. There was no evidence of statistically significant heterogeneity.

**Within Group Analyses:**

Psychological treatment was associated with moderate improvements in frequency (nine trials, REM: g=0.54, 95% CI: 0.29, 0.79) and intensity (eight trials, REM: g=0.54, 95% CI: 0.27, 0.80) of headaches and small improvements in duration of headaches (nine trials, REM: g=0.29, 95% CI: 0.04, 0.54) at end of treatment compared to pre-treatment levels. Participants in the psychological treatment group continued to show improvements on headache variables at follow-up (4 to 12 months) compared to pre-treatment levels (REM: g=1.00, 95% CI: 0.64, 1.33). There was no significant impact on use of medication. Use of medication and headache variables did not significantly change pre-treatment and post-treatment in the waiting list group. There was no evidence of statistical heterogeneity.

**Subgroup analyses:**

Relaxation and biofeedback treatments were both associated with a greater number of participants experiencing clinically significant levels of symptom reduction compared to waiting list controls: relaxation treatments (seven trials, REM: g=0.80, 95% CI: 0.23, 1.35); biofeedback treatments (four trials, REM: g=0.90, 95% CI: 0.10, 1.68). There was no difference between relaxation or biofeedback treatment groups and controls on headache variables. A subgroup analysis of migraine sufferers found that significantly more participants in the treatment group had clinically significant levels of symptom reduction compared to migraine sufferers in the control group (five trials, REM: g=1.22, 95% CI: 0.61, 1.84).

**Publication bias:**

Trim-and-fill analysis was applied to the findings to correct for possible publication bias, thereby reducing the effect sizes for between group analysis (headache variables, REM: g=0.23, 95% CI: -0.03, 0.50; clinical significance, REM: g=0.76 95% CI: 0.50, 1.02) and within group analyses (headache variables, REM: g=0.40, 95% CI:0.17, 0.61).

**Authors' conclusions**

The efficacy of psychological treatments in paediatric headache patients is supported at evidence level 1a (several consistent RCTs support efficacy). Treatment efficacy is demonstrated for up to 1 year and shows a trend for further improvement beyond this point.

**CRD commentary**

The review addressed a clear question and inclusion criteria for intervention. Study designs and participants were well defined. It is unclear whether the outcomes of medication use and the calculation of clinically significant change in symptoms were decided a priori, which may have introduced bias into the review process. Several relevant databases
were searched and attempts were made to identify unpublished material. The authors attempted to correct for publication bias. The search was restricted to articles in English and German, which may have introduced language bias. It is unclear whether appropriate methods were used in the study selection and data extraction, so the likelihood of reviewer error and bias cannot be ruled out. A formal validity assessment does not appear to have been carried out, therefore it is not possible to determine the quality of included studies. However, some studies showed a high number of drop-outs and it is unclear whether intention-to-treat analyses were applied; therefore bias may have been introduced. The decision to use a between group meta-analysis was appropriate and statistical heterogeneity was assessed. However, the averaging of effect sizes for studies with more than one outcome was inappropriate. The use of within groups meta-analysis was redundant and the absence of control group comparisons may have over emphasized treatment effects. Given the unclear quality of included studies and the potential for reviewer error and bias, the authors' conclusions should be treated with caution.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further research is needed exploring the differential outcomes between children with different headache diagnoses and the interaction between treatment and diagnosis. Future research should explore outcomes such as behavioural and cognitive coping, changes in cognition, self-efficacy, and health related attitudes and behaviour in order to explore the mechanisms of change. Disability and emotional distress as measured using adequate instruments should be included as future outcomes. The comparative efficacy of pharmacological and psychological treatments should be explored. Future research should be designed with active control groups and using intention-to-treat analyses.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract
contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.