CRD summary
This reasonably well-conducted review evaluated non-pharmacological migraine prophylaxes in children. The authors concluded that evidence of the effectiveness of relaxation, biofeedback and cognitive-behavioural therapy, instructions to improve sleep hygiene, or the use of special diets is limited, while evidence of the effectiveness of relaxation plus thermal biofeedback is moderate. The cautious conclusions are based on small studies but are likely to be reliable.

Authors' objectives
To assess the efficacy of non-pharmacological prophylactic interventions for the treatment of migraine in children.

Searching
MEDLINE, EMBASE, PsycINFO, Web of Science, CINAHL and the Cochrane Controlled Trials Register (Issue 2, 2004) were searched from inception to June 2004; the search terms were reported. No language restrictions were applied. Additional studies were sought through the reference lists of reviews and included studies.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and clinical controlled trials (CCTs) were eligible for inclusion.

Specific interventions included in the review
Studies of non-pharmacologic interventions for the treatment or management of migraine in children, with criteria that distinguished migraine from other types of headache, were eligible for inclusion. Studies that did not compare different interventions were excluded, as were studies that examined a pharmacological treatment of migraine. The interventions in the included studies were acupuncture, behavioural treatment (relaxation and cognitive-behavioural therapy, CBT) and lifestyle adjustments (instructions to improve sleep hygiene, red- and blue-tinted glasses, inclusion and exclusion of foods high in vasoactive amines, di- or oligoantigenic diet, fish oil and olive oil).

Participants included in the review
Studies of children under 18 years of age who had a diagnosis based on at least some of the distinctive features of migraine were eligible for inclusion. Such features included headache attack lasting 2 to 48 hours, unilateral location, pulsating quality, moderate to severe intensity, aggravated by routine physical activity, nausea and/or vomiting, photophobia and phonophobia. Studies that included participants without a diagnosis of migraine were excluded. The patients in the included studies had a mean age of 11.7 years (range: 3 to 18) and 55.6% were girls.

Outcomes assessed in the review
Studies with at least one of the following outcomes were eligible for inclusion: intensity, frequency, duration, headache or improvement of headache. Studies that did not have a separate analysis of migraine outcomes were excluded. All included studies used headache diaries to assess outcomes, with frequency, intensity and duration of headache scored on a Likert scale. Most of the included studies calculated a measure of clinical improvement, with a headache that declined by greater than 50% considered clinically relevant.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected the studies for inclusion. Any disagreements were resolved by consensus or through arbitration by a third party.

Assessment of study quality
Two reviewers independently assessed validity. Study quality was assessed based on a Delphi list with the following criteria: randomisation, allocation concealment, baseline comparability, specification of eligibility criteria, blinding,
presentation of point estimates and measures of variability, intention-to-treat analysis, and withdrawal and drop-out rate. Any discrepancies were resolved by consensus or by consultation with a third reviewer.

Data extraction
One reviewer extracted the data from the included studies and another reviewer checked the extraction. Any disagreements were resolved by consensus. The following data were extracted: demographic data, detailed description of the intervention and control, outcome measures and information on adverse events. Standard mean differences (SMDs) with 95% confidence intervals (CIs) were calculated for continuous outcomes and relative risks (RRs) with 95% CIs for dichotomous variables. Crossover trials were treated as parallel-group designs, with only data from the first period included.

Methods of synthesis
How were the studies combined?
Statistical pooling was performed if studies were found to be clinically homogeneous. If studies were not found to be clinically homogeneous, a qualitative analysis was performed using a rating system with levels of evidence. The evidence was considered strong when at least 2 high-quality RCTs produced generally consistent findings. The results were considered consistent if at least 75% of the studies reported similar results on the same outcome measure. Evidence was considered moderate when one high-quality RCT and/or at least 2 low-quality RCTs and/or CCTs produced generally consistent findings. Evidence was considered limited when only one low-quality RCT and/or CCT existed, and conflicting if the findings of existing trials were inconsistent. No evidence was considered when no RCTs or CCTs were found, or when the authors provided insufficient data for analysis.

How were differences between studies investigated?
Some discussion of differences between the studies was included in the narrative synthesis.

Results of the review
Nineteen studies (n=834) were included in the review: 17 RCTs (12 parallel-group design and 5 crossover design) and 2 CCTs.

The median score for methodological quality in the included studies was 4 (range: 2 to 7). When considering scores above 6 as high, only 2 studies were considered to have high quality; the most common shortcoming was blinding and allocation concealment.

Relaxation.
Two studies of very small sample size presented data with inconsistent results: comparison with waiting list showed a significant difference while comparison with placebo (attention) did not.

Biofeedback (6 studies).
One study compared biofeedback with placebo, two compared the additional effect of biofeedback on relaxation, or relaxation plus behavioural management, two compared biofeedback with waiting list, and one compared clinical-based thermal biofeedback with home-based thermal biofeedback. No statistically significant differences were found.

CBT (2 studies).
One study compared cognitive coping with placebo (attention) and one compared the effect of behavioural management of pain added to thermal biofeedback treatment. No significant differences were found post-treatment, but inconsistent results were found at 3 to 4 months' follow-up.

Combined behavioural treatments (6 studies).
Two studies compared relaxation combined with thermal biofeedback to waiting list. The pooled RR showed a significant post-treatment difference in favour of the intervention (RR 4.20, 95% CI: 1.79, 9.83). One study comparing relaxation plus CBT with waiting list showed no significant difference. One study comparing home-based relaxation
plus behavioural therapies with placebo showed a significant difference favouring the intervention (RR 2.78, 95% CI: 1.31, 5.90), but no significant difference between clinical-based relaxation plus CBT and home-based relaxation plus CBT, or between clinic-based relaxation plus CBT and placebo. One study compared relaxation and stress management with metoprolol or cephalic vasomotor feedback plus stress management and found no significant difference between groups. Two studies compared relaxation plus CBT plus biofeedback with waiting list, and the effect size post-treatment was significant in favour of the combined intervention (RR 2.84, 95% CI: 1.04, 7.77).

Other non-pharmacologic prophylactic treatments (7 studies).

One study evaluated instruction to follow guidelines towards improving sleep hygiene and found significantly lower headache frequency compared with the non-instruction group at 3 months' follow-up (RR 0.38, 95% CI: 0.15, 0.96) and 6 months' follow-up (RR 0.33, 95% CI: 0.12, 0.93). No difference was found in the use of red- or blue-tinted glasses.

One study showed that the exclusion of foods with vasoactive amines in a diet rich in fibre did not improve headache.

Two studies showed that oligoantigenic diets (diets that exclude milk, eggs, food additives and vasoactive amine-containing foods) are more effective than placebo (RR 0.23, 95% CI: 0.12, 0.47; RR 6.11, 95% CI: 2.12, 17.5). One high-quality study compared the use of fish oil with placebo (olive oil) and found no significant differences. Another small high-quality study compared acupuncture with placebo and found significantly lower headache in the intervention group (SMD -7.31, 95% CI: -9.84, -4.78).

Authors' conclusions
A few non-pharmacological treatments such as relaxation may be effective as prophylactic treatment for migraine in children. Conclusions on effectiveness have to be drawn with caution because of the small number of studies and the methodological shortcomings.

CRD commentary
This review addressed a clearly defined question and undertook a reasonably extensive search for published trials. No attempts were made to search for unpublished literature and the potential for publication bias was not considered. Inclusion and exclusion criteria for the study design, intervention, population and outcome were clearly stated. The study selection, validity assessment and data extraction processes were conducted in duplicate, thus reducing the potential for bias and error. The decision to employ meta-analysis for clinically homogeneous studies only appears appropriate. The conclusions seem likely to be reliable, but the small size and low quality of the included trials mean that they should be read in conjunction with the recommendations for further research.

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

Research: The authors stated the need for large, high-quality RCTs evaluating the most commonly offered non-pharmacological prophylactic treatments for migraine in children.

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