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Cognitive and Relaxation Treatment of Paediatric Migraine [1]

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Summary

The present study compared the efficacy of two active treatments, relaxation training and cognitive coping, with a non-specific placebo control in the treatment of 42 children and adolescents with migraine. The first treatment is a simplified version of progressive deep muscle relaxation; the second, a form of cognitive restructuring involving the alteration of dysfunctional thought processes. The results demonstrated that each active treatment was superior to the non-specific intervention in reducing overall headache activity and frequency but not duration or intensity. There were no differences between the experimental groups, and both continued to improve through a 16-week follow-up period, but the control group did not.

Initial level of headache severity was an important factor in treatment outcome, with children with severe headaches responding better than those with milder headaches.

Possible reasons for the differential treatment effects are discussed, and the implications for future research are considered.

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Introduction

A substantial and growing body of literature indicates that relaxation training, cognitive coping and biofeedback can all be effective in the treatment of adult migraine [6–8,15,18]. However, with one exception [8], interpretation is hampered by the use of only a waiting-list control group. Thus, it remains unclear whether non-specific effects alone can account for the observed superiority of the behavioural methods.

A number of studies have shown that biofeedback's effectiveness does not depend upon the successful acquisition of the specific targeted responses [11,19]. Rather, a generalized relaxation response, which is common to all of these treatments, may be operating. On the other hand, biofeedback may act by altering the patient's cognitive schema concerning the potential controllability of headaches and promoting cognitive coping [1,3,16]. Certainly recent reviews suggest that both cognitive coping and relaxation methods can attenuate a wide variety of clinical pain syndromes [25–27].

Paediatric migraine has a reported incidence of approximately 4–11% [4,5,22] (depending upon age, sampling, and diagnostic criteria), and it can present a management problem to the physician. Although several uncontrolled studies and single subject designs have reported success with behavioural interventions [12], there have been no controlled group outcome studies using cognitive coping and/or relaxation training with children. The purpose of the present study was to compare the effectiveness of these two methods to a credible placebo intervention in the management of paediatric migraine and to determine whether treatment gains would be maintained at a 16-week follow-up assessment.

Methods

Subjects

The subjects were 51 migraine patients, 9–18 years of age, referred to the Children's Hospital of Eastern Ontario (CHEO) by their physicians. There were 17 boys and 34 girls with a mean age of 12.87 years and a mean I.Q. of 108.67 on the Peabody Picture Vocabulary Test (PPVT). Most had been suffering from migraine for at least 2 years.

Participation required confirmation of the diagnosis of classical or common migraine by a project neurologist using the diagnostic criteria of intermittent paroxysmal headache and any 2 out of the following 4 symptoms: throbbing pain, scotomata or related neurologic phenomena, nausea and/or vomiting, and a positive family history. Other inclusion criteria were a minimum headache history of 3 months, an average frequency of once/week, no new prophylactic medication within the previous 2 months, and a minimum I.Q. of 80 on the PPVT. Children with allergic, purely dietary, or menstrual headache were excluded, as were those with unstable emotional or medical problems likely to require other interventions.

Procedures

The research design involved 4 distinct phases of continual headache monitoring: 4 weeks of baseline, 6 weeks of treatment, 4 weeks of posttreatment, and 4 weeks of follow-up from the twelfth to sixteenth week after treatment.

In the baseline phase, the rationale and methodology for the project were explained, and informed consent was obtained. Patients were then taught to monitor headache activity 4 times daily using a Headache Diary [10], which yields quantitative measures of pain intensity (rated 0–5 4 times daily), frequency, duration and medication used. Patients were also assessed with the State-Trait Anxiety Inventory (STAI) [24] or the State-Trait Anxiety Inventory for Children (STAIC) [23] and the Children's Depression Rating Scale [20] to ensure experimental group equivalence on initial levels of anxiety and depression which may moderate pain and response to treatment.

Following baseline, all subjects who met criteria were dichotomized for headache severity (mean weekly score on Headache Index of more than 20.66 points) and randomly assigned to treatment. All subjects received 1 h of individual therapy weekly, which followed detailed treatment manuals (available from Dr. McGrath) to standardize procedures. Sessions were taped and randomly monitored to encourage adherence to the manuals.

In the first session, all groups were given information about the nature of migraine, the role of stress and other triggers [29], and the specific treatment rationale was explained. To control credibility, the 3 rationales were identical except for slight differences in explaining the respective mechanisms of action. All treatments were presented as stress-coping techniques which could be used to reduce tension and anxiety and thereby short-circuit the migraine process. Credibility was checked after the first and last sessions to ensure that this variable was not confounded with treatment effects. To establish equivalence, all rationales had first been tested and modified as necessary in a pilot project [21].

Relaxation training. This treatment closely followed the procedure developed by Cautela and Groden for children [9]. Subjects were taught the sequential tensing and relaxing of large muscle groups and the use of deep breathing to achieve total body relaxation. They were then taught sequential relaxation without tensing, differential relaxation, self-cueing, and 'mini' relaxation. They were instructed to practice daily and to use their relaxation skills as soon as they noticed stress levels rising, if they were involved in a stress-producing situation, or at the onset of a headache.

Cognitive coping. This programme, called 'thinking straight,' was developed by the authors as a downward extension of Holroyd and Andrasik's [13] cognitive self-control programme and Bakal's [1] cognitive-behavioural treatment. It emphasized altering maladaptive thought processes which mediate unpleasant emotions and biochemical concomitants which may precipitate the headache process. The programme used elements of cognitive restructuring, the cognitive control of pain, fantasy, simple problem solving, and stress-inoculation training [17]. Children were taught to monitor their stress reactions on a daily basis, to record and restructure thought processes, and to note the emotional correlates of their cognitive patterns. They were instructed to use the procedures in all stress-provoking situations as well as for the control of headache pain. Personalized cards containing coping statements were prepared for each subject; e.g. I'm an O.K. kid even if I don't do so well in math,' or 'I can cope with this headache; I won't let it get to me.'

Placebo treatment. This was an attention-control or non-specific condition called 'stress reduction training.' Structurally it was identical to the experimental groups, i.e., it provided information on the causes of migraine, a credible treatment rationale, expectations for improvement, a set of sham 'coping skills,' and daily homework. Basically, subjects were taught to recognize and label their emotions, to relate them to the situation in which they occurred, and to discuss their feelings daily with a friend or parent. This treatment is a credible placebo, not unlike non-directive psychotherapy. However, it does not contain any theoretically active treatment components.

Results

Over the course of treatment there were 8 drop-outs, and 1 child failed to monitor adequately during follow-up. This left 42 subjects, 15 in each experimental group, and 12 in the placebo condition. A chi-square analysis comparing attrition rates across interventions was not significant. Moreover, analyses of variance and Hartley's F maximum tests suggested that the final groups were approximately equivalent on demographic, personality, and headache variables at baseline. Therefore, it was not necessary to partial out the effects of anxiety and depression on treatment outcome.

Effects of treatment on migraine activity

To clarify this issue and evaluate the maintenance of treatment gains during follow-up, headache data were analysed as a $3 \times 2 \times 2$ randomized factorial experiment, with repeated measures on the last factor, i.e., posttreatment and follow-up [28]. The first factor was treatment group, and the second, initial level of headache severity. Following a significant F test or Dunn's planned comparison test, within-group changes were evaluated by one-tailed t tests. Significant interactions were assessed for simple main effects and the Newman–Keuls test if warranted [14].

The major dependent variables were all derived from the Headache Diary. They were the Headache Index, Frequency, Mean Duration, and Peak Intensity. A medication count was calculated, but not analysed, because most subjects took little, if any, medication. Tables I–III provide means and standard deviations for the 4 headache variables according to treatment group, severity level, and time of assessment. Fig. 1 presents the major results in terms of changes in the Headache Index over the course of the experiment.

Two significant main effects occurred on all measures: (1) the severity factor was always significant ($P < 0.001$), and (2) there was a significant time effect on the repeated measure ($P < 0.001$). This indicated that, overall, subjects were more improved at follow-up than they were at posttreatment. Beyond these omnipresent effects, the Headache Index yielded a trend toward a significant main effect for the

TABLE I

MEANS AND STANDARD DEVIATIONS OF HEADACHE FREQUENCY FOR GROUPS AND LEVEL OF SEVERITY

Group	n	Baseline		Posttest		Follow-up	
		x̄	S.D.	x̄	S.D.	x̄	S.D.
Relaxation	15	9.03	(8.05)	5.17	(5.16)	2.91	(3.40)
Low	7	3.21	(1.82)	1.36	(1.25)	1.14	(1.64)
High	8	14.13	(7.94)	8.51	(4.97)	4.47	(3.86)
Cognitive	15	8.14	(7.82)	4.50	(5.29)	2.52	(2.94)
Low	8	3.32	(1.62)	1.96	(1.84)	1.10	(1.10)
High	7	13.64	(8.55)	7.39	(6.55)	4.14	(3.61)
Placebo	12	7.26	(6.12)	6.45	(6.09)	4.68	(5.83)
Low	7	2.56	(0.90)	1.89	(1.75)	0.91	(0.59)
High	5	13.85	(2.98)	12.83	(3.20)	9.95	(5.77)

TABLE II

MEANS AND STANDARD DEVIATIONS OF HEADACHE PEAK INTENSITY FOR GROUPS AND LEVEL OF SEVERITY

Group	n	Baseline		Posttest		Follow-up	
		x̄	S.D.	x̄	S.D.	x̄	S.D.
Relaxation	15	3.60	(1.08)	2.52	(1.19)	2.08	(1.73)
Low	7	2.79	(0.92)	1.79	(1.12)	1.14	(1.43)
High	8	4.31	(0.59)	3.17	(0.86)	2.91	(1.61)
Cognitive	15	3.37	(0.77)	2.52	(1.14)	1.96	(1.23)
Low	8	3.13	(0.95)	2.16	(1.27)	1.67	(1.30)
High	7	3.65	(0.37)	2.94	(0.88)	2.29	(1.16)
Placebo	12	3.58	(0.76)	2.39	(1.33)	2.02	(1.39)
Low	7	3.11	(0.28)	1.54	(0.99)	1.21	(0.73)
High	5	4.25	(0.72)	3.58	(0.57)	3.15	(1.34)

TABLE III

MEANS AND STANDARD DEVIATIONS OF HEADACHE DURATION FOR GROUPS AND LEVEL OF SEVERITY

Group	n	Baseline		Posttest		Follow-up	
		x̄	S.D.	x̄	S.D.	x̄	S.D.
Relaxation	15	1.80	(0.92)	1.36	(0.65)	0.88	(0.80)
Low	7	1.20	(0.44)	0.91	(0.65)	0.49	(0.62)
High	8	2.32	(0.92)	1.74	(0.33)	1.23	(0.81)
Cognitive	15	1.81	(0.83)	1.34	(0.87)	0.89	(0.68)
Low	8	1.44	(0.67)	1.19	(1.07)	0.63	(0.54)
High	7	2.24	(0.84)	1.50	(0.60)	1.20	(0.72)
Placebo	12	1.68	(0.61)	1.45	(0.89)	1.08	(0.81)
Low	7	1.43	(0.69)	0.93	(0.74)	0.57	(0.31)
High	5	2.02	(0.22)	2.18	(0.48)	1.79	(0.77)

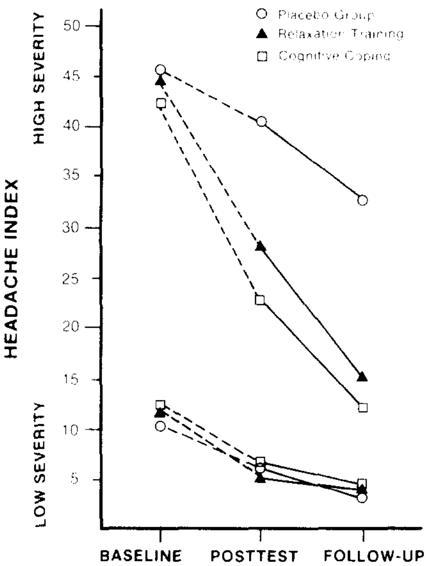

Fig. 1. Mean Headache Index at baseline, posttest and follow-up according to treatment group and level of severity.

treatment factor, F (2, 36) = 2.94, $P = 0.066$, and a significant main group effect occurred on Headache Frequency, F (2, 36) = 3.54, $P < 0.05$. An examination of the group means suggested that, as was hypothesized, both active treatment groups reported less overall headache activity and lower frequency after treatment and at follow-up than the placebo group. This was confirmed for both variables using Dunn's a priori planned comparisons ($P < 0.05$) and supported the major hypotheses of the study.

It was also found that the group and severity factors interacted significantly, F (2, 36) = 3.55, $P < 0.05$ on the Headache Index, and F (2, 36) = 3.54, $P < 0.05$ on Frequency. This indicated that the differences among the interventions following treatment depended upon both group membership and initial level of severity. A test of these interactions for simple main effects showed no differences among the groups at the low level of severity, but a significant difference among treatment groups at the high severity level, F (05/3, 36) = 5.72 and 6.50 for the Index and Frequency respectively. (These tests followed Dunn's procedure to hold the overall error rate at 0.05.) Newman–Keuls comparisons established that, at the high severity level, the cognitive coping group had significantly less headache activity than the high severity placebo group on both variables ($\bar{\psi} = 17.53$, and 5.62, $P < 0.05$). Similar results were obtained in comparing relaxation with placebo on Headache Frequency ($\bar{\psi} = 4.90$, $P < 0.05$), but there was only a trend ($P < 0.10$) on the Headache Index. There were no significant differences between the active treatment groups on either variable.

Another result was the failure to obtain a significant group-by-time interaction. This indicated that the observed group differences on both dependent measures were maintained at the follow-up. This was confirmed with within-groups t tests, which indicated that, on the Headache Index, both the relaxation and cognitive groups continued to improve between the posttreatment and follow-up, $t\ (14) = 2.11$, $P < 0.05$, and $t\ (14) = 2.48$, $P < 0.025$, while the placebo group did not. Comparable significant improvement occurred on Headache Frequency.

Discussion

Generally, the results supported the major hypothesis of this study. Both the relaxation and cognitive coping groups had significantly fewer headaches and less overall headache activity after treatment than did the placebo control group. Moreover, they maintained their gains, and they continued to improve between the 4-week posttest and the 16-week follow-up, while the control group did not. The active treatment groups did not differ on any measure.

These results are generally consistent with those reported in the adult migraine literature on relaxation [7] or cognitive training [15]. However, both of these studies used a waiting-list control, and the literature on tension headaches suggested that placebo effects alone could be operative. The present results demonstrate that, in paediatric migraine, both active behavioural interventions were superior to a placebo condition under stringent conditions of controlled experimenter demand and equivalent credibility. In earlier work, the theoretically active components and credibility were usually confounded.

The lack of a significant response in terms of Headache Duration and Peak Intensity was not expected. It is possible that these variables are indeed less responsive to treatment than Headache Index and Frequency. The former is a sensitive, multifaceted measure of overall headache activity which is generally regarded as the best indicator of activity because it responds to improvement on any or all dimensions. It is possible that Headache Frequency is the most responsive single dimension because behavioural programmes may sensitize the migraineur to identify precursor symptoms and to initiate coping responses which abort the headache process but do not alter its course once it begins.

Another finding was the moderating effect of initial headache severity on treatment outcome. Although both active treatment groups improved significantly on the Headache Index and Frequency compared to the placebo group, the response to treatment was significantly superior in the severe condition. It is unlikely that regression to the mean can account for the differential results since one would expect equal regression among the interventions. This result has not been demonstrated before, and it suggests that differences in initial severity may explain some of the contradictions in the adult migraine literature. Although Bakal observed that patients with almost continual pain were the most refractory to treatment [2], it may be that severe migraine is amenable to treatment if it has not yet progressed to the point of chronic, intractable pain which has become the focus of an entire lifestyle. Or, children may be more responsive than adults.

Research is required to evaluate how such factors as age, acuteness, chronicity or cyclicality, and variability of pain intensity affect outcome. In the interim it is incumbent upon researchers to clearly document their subject selection criteria.

The observed superiority of the active treatments over the non-specific condition requires some explanation. Recent theories of mechanisms of change in migraine have hypothesized possible behavioral and cognitive mechanisms. Among the alternatives are: a general relaxation response and a concomitant decrease in autonomic arousal; the acquisition of one or more coping skills which may be applied to precipitating stressors and/or headaches per se; or cognitive or attitudinal changes in the appraisal of the self and environmental demands, and an emerging perception of self-efficacy [3]. These mechanisms of change are not necessarily mutually exclusive. Indeed, they may co-exist and enhance each other leading to a potential additive effect. Further research is obviously required to elucidate this issue.

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