

# RELAXATION PROPHYLAXIS FOR CHILDHOOD MIGRAINE: A RANDOMIZED PLACEBO-CONTROLLED TRIAL

*P. J. McGrath*  
*P. Humphreys*  
*J. T. Goodman*  
*D. Keene*  
*P. Firestone*  
*P. Jacob*  
*S. J. Cunningham*

Migraine headaches are common in children and adolescents and their occurrence increases with age, from approximately 1.4 per cent of seven-year-olds to 5.3 per cent of 15-year-olds (Bille 1962). When frequent and severe headaches cannot be adequately controlled by analgesics they become a difficult management problem. Almost all drugs used for adult migraine sufferers have been suggested for children with migraine, but there are few properly controlled studies. Indeed, propranolol is the only drug to have been adequately evaluated. Ludvigsson (1974) reported excellent results in an early study, but a recent well-controlled trial by Forsythe *et al.* (1984) failed to demonstrate the efficacy of propranolol, and in fact suggested that it may exacerbate paediatric migraine.

A number of poorly controlled studies (e.g. Diamond and Franklin 1975) and single-case experimental studies (Andrasik *et al.* 1982, Labbe and Williamson 1983) have suggested that various psychological therapies may be effective for paediatric migraine. Two randomized trials by Labbe and Williamson (1984) and Fentress *et al.* (1986) used waiting-list controls and demonstrated the effectiveness of psychological treatment for this disorder.

Labbe and Williamson (1984) compared the effects of autogenic feedback in a waiting-list control group and in 28 children with migraine aged between seven and 16 years. Using a criterion of 50 per cent reduction in headaches as clinical improvement, 93 per cent of the autogenic group had improved at the end of treatment and at one-month follow-up, compared with only 7 per cent of the control group at the end of treatment and 14 per cent at follow-up.

Similarly, Fentress *et al.* (1986) randomly assigned 18 children with migraine between the ages of eight and 12 years to one of three groups: relaxation-response, relaxation-response plus bio-feedback, and waiting-list control. The results for the two active-treatment groups were superior to those for the control group, and were equivalent to each other. Treatment effectiveness was maintained at one-year follow-up. Those researchers noted that both active-treatment groups had received brief counselling for the management of pain, which could be construed as a confounding factor, and that future studies should include an attention control or placebo group.

In an earlier study, we compared the effects of relaxation training and cognitive therapy with a credible

psychological placebo consisting of discussions with the children about identification and expression of their feelings (Richter *et al.* 1986). The effects of the two active treatments were significantly superior to the placebo, but only for the children with severe migraine. Children with less severe migraine did as well on the placebo as on active treatment. However, our psychological placebo involved lengthy discussions of the child's feelings, so it is not possible to be sure that active psychotherapy was not involved.

We undertook the present study to replicate and extend our previous work. In particular, we wished to add a credible treatment that did not include extensive involvement with a therapist or the teaching of complex skills. We have been particularly concerned about the use of adequate control groups, since we believe that a waiting-list control group is insufficient in that it does not control for expectancies. Migraine sufferers who are assigned to a waiting list may expect that their headaches will stay the same until they receive treatment, and may even maintain their headache reports to ensure that they do receive treatment. Control for expectancies may be particularly important in investigations of pain disorders such as headache that rely on subjective reporting of symptoms (Fentress *et al.* 1986). Placebo control is standard in the evaluation of pharmacological treatment for headache; although psychological placebos are more difficult to implement, they are equally important.

### Subjects

Ninety-nine children and adolescents (30 male, 69 female) aged between nine and 17 years (mean 13.1 years) completed this study. All had been referred by their paediatricians or family physicians to the migraine clinic at the Children's Hospital of Eastern Ontario and were initially examined by a paediatric neurologist to confirm the diagnosis. Children were included in the study if they met the following criteria for migraine: intermittent, paroxysmal headache over a period of at least three months, with an average frequency of one per week, and

any two of the four symptoms of throbbing pain, visual or sensory prodromes, nausea or vomiting, or a positive family history. Children were excluded from the study if they did not have a minimum IQ of 80 on the Peabody Picture Vocabulary Test, if new medication had been commenced for the treatment of headaches, or if they had unstable psychological or medical problems that were likely to require other interventions. Parents and children provided written, informed consent.

### Procedures

The children were required to complete headache diaries for a four-week baseline period, six weeks of treatment and four weeks post-treatment. Diaries were also completed for four-week periods at three months and one year post-treatment. The diary required headache intensity to be rated four times a day on a scale from 0 to 5. There is also provision for reporting medication taken and suspected cause of the headache. These diaries have demonstrated validity in reporting paediatric migraine (Richardson *et al.* 1983, Andrasik *et al.* 1985).

Following the baseline recordings, the children were stratified by age, sex and headache severity and randomly assigned to one of three groups: relaxation training, psychological placebo or 'own best efforts'. In the first session following the baseline period, all the children were told that migraine was a physiological disorder, often precipitated by stress and other triggers. They were told that their treatment would help them identify and modify these triggers and would lead to a reduction in their headaches.

Relaxation training consisted of a series of six individual, one-hour, weekly sessions with a therapist, in which a modification of the method of Cautela and Groden (1978) was used. The children were taught sequential tensing and relaxation 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. Differential relaxation consisted of learning to relax parts of the body while other parts remained tense;

TABLE 1  
Credibility of treatment

Group	After	first	Post-treatment	
	session Mean	SD	Mean	SD
Relaxation (N = 32)	12.7	3.1	13.1	1.9
'Own best efforts' (N = 30)	12.0	2.6	11.8	3.3
Placebo (N = 37)	12.7	2.6	13.2	1.8

Scores are based on four questions rated 0 to 4.

for example, they learned to relax the shoulders while standing with legs tense. Self-cueing consisted of reminders to practise relaxation: for example, adhesive stickers on textbooks to remind children to relax. 'Mini' relaxation were 30-second sessions in which controlled breathing was used to increase relaxation. The children were instructed to practise daily and to use their relaxation skills to counter stress and to cope with stressful situations and the onset of headaches.

Placebo treatment consisted of six individual, one-hour, weekly sessions with a therapist, in which children were taught to recognize and label their emotions, to relate them to their life situation, and to discuss their feelings daily with a friend or parent. Our intention was to provide a non-specific or attention-control treatment and to equate therapist contact with the relaxation treatment.

'Own best efforts' treatment consisted of a single session to discuss the use of the headache diary to determine what was triggering the migraine attacks. The diaries for the baseline period were reviewed and suggestions for strategies to reduce the impact of possible triggers were both elicited from and supplied to each child. There was no further contact with a therapist. We felt that this treatment would serve as an adequate control for therapist contact and active psychological treatment or psychotherapy that might inadvertently occur in the psychological placebo. After treatment the children in this group were offered relaxation training if their headaches continued to be a problem.

Each type of treatment was based on a detailed manual and all sessions were

audiotaped. The senior author reviewed a random sample of audiotapes to ensure compliance with the treatment protocol. The three therapists were experienced in the three methods, and each conducted an equal share of all three types of intervention.

### Measures

Two types of measures were used to evaluate the three types of treatment. Credibility measures were derived from questionnaires administered at the end of the first treatment session and again after treatment. The children were asked to rate four items on a scale from 0 to 4. The items focused on the logic of the treatment, their confidence in recommending the treatment to others, their confidence that treatment would reduce headaches, and their confidence that children could learn the techniques. As well, following treatment the children were asked to rate on the same scale from 0 to 4 how skilled their therapist was, how understanding and how warm and friendly she was.

Headache measures were derived from the headache diary and included a headache index (the sum of all 28 ratings in one week)—headache-free days, headaches greater than scale 2, and highest weekly rating.

### Results

Thirty-seven children dropped out before the end of treatment (12 relaxation training, 16 placebo, nine 'own best efforts'). Analysis revealed no significant differences in attrition ( $\chi^2 = 2.0$ ,  $p = 0.26$ ). This left 32 children in the relaxation group, 30 in the placebo group and 37 in the 'own best efforts' group.

The children dropped out mainly because their treatment was ineffective and they were not systematically tried on other treatments. (We have found that few children will consent to prophylactic drug treatment.)

The three groups were equivalent in credibility after the first session and maintained their belief in the treatment they were receiving (Table I). Table II shows their ratings of the therapists following treatment.

The mean headache indices for the three treatment groups and for the high- and low-severity subgroups are shown in Table III. Three repeated-measures analyses of variance (baseline and post-test; baseline, post-test and three-month follow-up; and baseline, post-test, three-month and 12-month follow-up) consistently revealed significant differences due to severity ( $p < 0.05$ ) and significant effects over time ( $p < 0.05$ ), but no significant effect of group and no group  $\times$  time interaction. All the other headache variables (headache-free days, headaches greater than scale 2, highest weekly rating) followed the same pattern.

### Discussion

Patients in all three treatment groups showed a significant reduction in headaches following treatment and the reduction was still evident at 12-month follow-up. This suggests that a credible treatment method which includes suggestions of techniques for self-control of headaches may be a prime factor in the effectiveness of psychological treatment of paediatric migraine.

TABLE II  
Children's ratings of therapists following treatment

Group	Ratings	
	Mean	SD
Relaxation	11.5	0.95
'Own best efforts'	10.9	1.4
Placebo	11.3	0.95

Scores are based on three questions rated 0 to 4.

We found no superiority for relaxation training in reducing headaches over the other two forms of treatment. The placebo treatment did involve lengthy discussions of a psychological nature, which might be seen as a type of therapy, but the 'own best efforts' patients were seen for only one session, which was very highly structured, and could not have learned a form of relaxation by accident. Since we were the only group in our area offering formal relaxation treatment to children, and we queried our patients about attendance for other treatments, we are confident that our treatments were not contaminated. Our findings suggest that relaxation training is no more effective in treating paediatric migraine than the 'own best efforts' approach, which does not involve specific training or lengthy contact with a therapist.

Since our present study used the same therapists and methods as our previous study (Richter *et al.* 1986), we can offer no explanation for the contradictory findings, except that the previously reported effect may not be robust. The trials reported by Labbe and Williamson

TABLE III  
Headache indices before treatment, after treatment and at follow-up

Group	Baseline		Post-treatment		3-month follow-up		12-month follow-up	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Relaxation								
Low severity	11.6	5.1	8.2	9.4	7.9	8.7	7.0	8.4
High severity	53.5	24.1	32.3	22.1	21.3	21.4	23.1	21.2
'Own best efforts'								
Low severity	9.7	4.9	7.7	9.5	—	—	—	—
High severity	41.2	16.0	27.2	17.4	—	—	—	—
Placebo								
Low severity	10.4	4.7	4.8	5.1	4.7	9.1	4.1	8.7
High severity	42.6	17.0	27.2	17.7	24.1	21.3	25.0	16.4

(1984) and Fentress *et al.* (1986) did not contain a placebo control group, and their results may be due to the control group's lower expectancies of relief.

Our results are supported by the observations of Prenskey and Sommer (1979) that half of all children with migraine who are seen in a neurology clinic, diagnosed and counselled, remit within six months. It may be that such patients are most likely to be seen in a specialty clinic at the height of the natural waxing of the disorder, which then will wane with time. The natural variation in paediatric migraine is in contrast to the more consistent picture in adults. The reason for this variation is unknown, but it may be because of changes in life stresses or biological changes. On the other hand, attending a clinic and receiving brief reassurance and assistance may be sufficient to give relief. Alternative forms of psychological treatment such as biofeedback training or cognitive restructuring, or longer or more comprehensive treatments that give children a variety of coping skills, may be more consistently effective. However, our

results draw attention to the need for replication and the necessity of providing adequate controls with equivalent expectancies in all therapeutic trials.

*Accepted for publication 3rd December 1987.*

#### *Acknowledgements*

Research supported by the Ontario Ministry of Health, Ontario Ministry of Community and Social Services and the Children's Hospital of Eastern Ontario. Dr. McGrath is supported by a Career Scientist Award of the Ontario Ministry of Health.

#### *Authors' Appointments*

\*P. J. McGrath, Ph.D., Department of Psychology, Children's Hospital of Eastern Ontario, 401 Smyth Road, Ottawa K1H 8L1; Departments of Psychology and Paediatrics, University of Ottawa. P. Humphreys, M.D.C.M., F.R.C.P.C.; D. Keene, M.D., F.R.C.P.C.;

P. Jacob, M.D., F.R.C.P.; Division of Neurology, Children's Hospital of Eastern Ontario; Department of Paediatrics, University of Ottawa.

J. T. Goodman, Ph.D., Department of Psychology, Children's Hospital of Eastern Ontario; Department of Psychology and Paediatrics, University of Ottawa.

P. Firestone, Ph.D., Child Study Centre, University of Ottawa.

S. J. Cunningham, M.A., Department of Psychology, Children's Hospital of Eastern Ontario.

\*Correspondence to first author.

#### SUMMARY

A randomized controlled trial was used to evaluate the effectiveness of relaxation training in the treatment of paediatric migraine. Relaxation training was compared with two control groups (psychological placebo and 'own best efforts') in a total of 99 children and adolescents with frequent migraine. Daily recording of the headaches following treatment, three months after treatment and at the one-year follow-up indicated that all three treatments were equally effective. The importance of the use of adequate control conditions which generate equivalent expectancies in pain treatment research was confirmed.

#### RÉSUMÉ

*Relaxation prophylactique dans la migraine de l'enfance: un essai randomisé avec contrôle placebo*  
Un essai contrôlé randomisé a été utilisé pour évaluer l'efficacité d'un entraînement à la relaxation dans le traitement de la migraine chez l'enfant. L'entraînement à la relaxation a été comparé avec deux groupes contrôle (placebo psychologique et 'faire de son mieux'), le tout formant un total de 99 enfants et adolescents fréquemment sujets aux migraines. Le relevé journalier des maux de tête à la suite de traitement, trois mois plus tard et après un an de suivi, a montré que les trois traitements étaient également efficaces. L'importance de l'usage de traitements contrôlés adéquats générant des espoirs identiques, dans la recherche sur le traitement de la douleur, est soulignée.

#### ZUSAMMENFASSUNG

*Prophylaxe durch Relaxation bei Migraine im Kindesalter: ein randomisierter, durch Placebo kontrollierter Versuch*

Durch einen randomisierten, kontrollierten Versuch wurde die Wirksamkeit eines Entspannungstrainings bei der Behandlung der kindlichen Migraine überprüft. Bei insgesamt 99 Kindern und Jugendlichen mit häufiger Migraine wurde das Entspannungstraining mit zwei Kontrollgruppen verglichen (psychologisches Placebo und 'bestmögliche eigene Bemühungen'). Tägliche Protokolle über die Kopfschmerzen nach der Behandlung, drei Monate danach und ein 1. später zeigten, daß alle drei Behandlungen gleich wirkungsvoll waren. Dies bestätigt die Bedeutung der Anwendung angemessener Kontrollbehandlungen in der Schmerztherapieforschung, die die gleichen Erwartungen wecken.

## RESUMEN

### *Relajación profiláctica de la migraña infantil: ensayo controlado al azar con placebo*

Se utilizó un ensayo controlado al azar para evaluar la eficacia del entrenamiento de la relajación en el tratamiento de la migraña infantil. El entrenamiento de la relajación se comparó con dos grupos control (placebo psicológico y 'los mejores esfuerzos propios') en un total de 99 adolescentes y niños con migraña frecuente. El registro diario de las cefaleas durante el tratamiento, tres meses después del mismo y al año de seguimiento, mostró que los tres tratamientos eran igualmente efectivos. Se confirma la importancia de un uso adecuado de los tratamientos con control adecuado, que generan expectativas equivalentes en la investigación del tratamiento del dolor.

### References

- Andrasik, F., Burke, E. J., Attanasio, V., Rosenblum, E. L. (1985) 'Child, parent and physician reports of a child's headache pain: relationships prior to and following treatment.' *Headache*, **25**, 421-425.
- Bille, B. (1962) 'Migraine in school children.' *Acta Paediatrica Scandinavica*, **51**, Suppl. 136, 1-151.
- Cautela, J., Groden, J. (1978) *Relaxation: a Comprehensive Manual for Adults, Children and Children with Special Needs*. Champaign, IL: Research Press.
- Fentress, D. W., Masek, B. J., Mehegan, J. E., Benson, H. (1986) 'Biofeedback and relaxation-response training in the treatment of pediatric migraine.' *Developmental Medicine and Child Neurology*, **28**, 139-146.
- Forsythe, W. I., Gillies, D., Sills, M. A. (1984) 'Propranolol ('Inderal') in the treatment of childhood migraine.' *Developmental Medicine and Child Neurology*, **26**, 737-741.
- Labbe, E. L., Williamson, D. A. (1983) 'Temperature biofeedback in the treatment of children with migraine headaches.' *Journal of Pediatric Psychology*, **8**, 317-326.
- — (1984) 'Treatment of childhood migraine using autogenic feedback training.' *Journal of Consulting and Clinical Psychology*, **52**, 968-976.
- Ludvigsson, J. (1974) 'Propranolol used in prophylaxis of migraine in children.' *Acta Neurologica Scandinavica*, **50**, 109-115.
- Prensky, A. L., Sommer, D. (1979) 'Diagnosis and treatment of migraine in children.' *Neurology*, **29**, 506-510.
- Richardson, G. M., McGrath, P. J., Cunningham, S. J., Humphreys, P. (1983) 'Validity of the headache diary for children.' *Headache*, **23**, 184-187.
- Richter, I. L., McGrath, P. J., Humphreys, P. J., Goodman, J. T., Firestone, P., Keene, D. (1986) 'Cognitive and relaxation treatment of paediatric migraine.' *Pain*, **25**, 195-203.