Biofeedback in the Treatment of Headache and Other Childhood Pain

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Since the first biofeedback (BFB) studies on pediatric pain were published in the early 1980s, most of the studies have focused on the treatment of pediatric migraine. More recently, BFB has also been evaluated in the treatment of tension headache in children. Not surprisingly, most of what we know about the efficacy and mechanisms of BFB in the treatment of children's pain problems concerns the treatment of childhood headache (HA). In this review, we provide a detailed summary of studies that have evaluated BFB in the treatment of childhood HAs with an emphasis on treatment outcome and maintenance of treatment success. Moreover, findings and hypotheses with regard to the mechanisms that may mediate the treatment of pain in children with BFB and outline future directions of research.

KEY WORDS: childhood pain; pediatric headache; biofeedback; efficacy; treatment mechanisms.

INTRODUCTION

Children experience pain from a number of different sources. Pediatric pain problems that have been the target of medical and/or psychological interventions are procedure-related pains (e.g., venipuncture, bone marrow aspiration), disease- or trauma-related chronic pain (e.g., rheumatoid arthritis, cancer, sickle cell anemia, burns), and recurrent pain of benign origin (e.g., primary headaches [HAs], abdominal pain).

Aside from acute pain, recurrent pain without an underlying disease is the most common type of pain condition during childhood and adolescence. The prevalence of HA, and especially migraine has been most extensively studied (for a general review, see Goodman & McGrath, 1991). Migraine has been estimated to affect between 3 and 10% of children and adolescents depending on age and sex (e.g., Linet, Stewart, Celentano, Ziegler, & Sprecher, 1989; Sillanpäa, 1983a, 1983b). The total prevalence of HA tends to be somewhat higher (Passchier & Orlebeke, 1985) and seems to have increased over the past 25 years.

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For example, Sillanpäa and Anttila (1996) found that HA had a prevalence of 51.5% among 7-year-olds in 1992 as compared to 14.4% in 1974. Weekly HAs may affect up to 30% of children and adolescents aged 10–17 years (Mikkelsson, Salminen, & Kautiainen, 1997; Passchier & Orlebeke, 1985; Rhee, 2000). The specific prevalence of tension HA is unknown, because most epidemiological studies did not apply adequate diagnostic criteria. Recurrent abdominal pain (RAP) has been estimated to occur in approximately 10–15% of school-aged children (Apley, 1975; Faull & Nicol, 1986; Hyams, Burke, Davis, Rzepski, & Andrulonis, 1996; Oster, 1972). Recent epidemiological surveys suggest that weekly nonspecific musculoskeletal pains may affect up to one third of school children between the ages of 9 and 12 years and persist in about half of these children at least for 1 year (Mikkelsson, Salminen, & Kautiainen, 1997; Mikkelsson, Salminen, Sourander, & Kautiainen, 1997).

Despite the obviously common occurrence of recurrent pain in children and adolescents, conclusions with regard to its severity and with regard to recurrent pain as a health problem are difficult to draw. In fact, the majority of children tend to cope quite well and never seek medical/psychological treatment. Because of the rather soft criteria used to assess HA (except migraine) and other pain problems in most studies, the prevalence data are likely to overestimate the actual need for treatment in children. Although they are scarce, prognostic data suggest that about a third of children reporting recurrent pains will simply outgrow this problem (Bille, 1989; Mikkelsson, Salminen, Sourander, et al., 1997). Yet, in a subgroup of children, recurrent pain tends to persist. In a 5-year follow-up, children with RAP were more likely to suffer from abdominal pain and other somatic symptoms and reported higher levels of functional disability than did control children (Walker, Garber, Van Slyke, & Greene, 1995; Walker, Guite, Duke, Barnard, & Greene, 1998). An impressive 30-year follow-up of Swedish pediatric migraineurs revealed that one third of the children continued to suffer from migraine throughout the 30-year period (Bille, 1989). Furthermore, in a recent longitudinal study it was found that children who complained about HAs at least once a month at age 7, 9, or 11 were more likely to have developed combined HA at age 26 (Waldie, 2001). Thus, recurrent pain during childhood may increase the risk of a lifetime of chronic pain, at least in a subgroup of children. From this perspective, the treatment of recurrent pain in children and adolescents is not only important as a primary intervention (at least for some of the children), but may also constitute an important measure of secondary prevention.

BIOFEEDBACK FOR CHILDHOOD PAIN AND THE EMPIRICAL LITERATURE

Since the mid-1970s when the undertreatment of pain in children was beginning to be acknowledged, increasing efforts have been made to develop psychological pain management programs for children. Cognitive–behavioral treatments exist for almost all of the different types of childhood pain, whereas biofeedback (BFB) treatments have primarily been developed and evaluated for recurrent pain conditions. Skin temperature or thermal biofeedback (TBF; i.e. volitional handwarming) and EMG-BFB from the m. frontalis are the types of BFB that have been evaluated most often in the treatment of childhood (and adult) pain.

Searching PsychInfo or Medline using variations of key words such as pain, BFB child/pediatric/adolescent yields about 50 publications since 1980. A closer look reveals that a substantial number are reviews and overviews describing the usefulness of BFB in

the treatment of HA (e.g., Holden, Deichmann, & Levy, 1999), disease-related symptoms (e.g., McQuaid & Nassau, 1999), chronic pain (e.g., Murphy & Carr, 2000), or childhood disorders in general (e.g., Barowsky, 1990; Culbert, Kajander, & Reaney, 1996). In fact, there are about as many reviews and overviews as there are empirical studies that provide actual treatment data based on controlled single-case or group studies.

In our review, we attempt to provide a summary of the available empirical evidence for the effectiveness of BFB for different childhood pain problems, address treatment mechanisms, and discuss child-related issues of BFB treatments. Because of the preponderance of BFB treatment studies for childhood HA, our review will largely have to rely on what is known about the use of BFB in the treatment of child HA.

CHILDHOOD PAIN AND THE EFFECTIVENESS OF BFB TREATMENTS

Pediatric Migraine

The vast majority of BFB treatment studies that have been published since the mid-1980s has been devoted to pediatric migraine. As can readily be seen in the summary of these studies in Table I, TBF alone, or in combination with other interventions, has been studied most extensively.

With few exceptions (e.g., Allen & Shriver, 1998, condition "TBF alone"), TBF has been proven to be highly successful in alleviating HA activity in children. In fact, in most studies more than two thirds of the children could be classified as treatment successes based on the widely accepted criterion of a 50% symptom reduction (Blanchard & Schwarz, 1988). If one considers the effect sizes (ESs) based on the pre- to postimprovement⁴ ("within-group" ES; for details, see Hermann, Kim, & Blanchard, 1995), the average ES of 2.2 suggests excellent efficacy. Moreover, the average ES based on all studies published since the 1980s (with the exception of Labbé, 1995) is comparable to the ES of 2.57 we had reported in our 1995 review based on a total of five studies. This suggests a considerable robustness of TBF efficacy across studies. Unfortunately, TBF has not directly been compared to a credible placebo condition or other potentially efficacious treatments such as cognitive behavior therapy (CBT) in children. If the evaluation criteria of the Task Force on Promotion and Dissemination of Psychological Procedures (1995) are applied, TBF for pediatric migraine is to be categorized as probably efficacious, but does not qualify as a well-established intervention (as it does for adults) that requires the demonstrated superiority over placebo or other alternative treatments.

Although the studies summarized in Table I leave little doubt that TBF is efficacious, treatment outcome is somewhat heterogeneous across studies. Aside from methodological differences, the format of treatment delivery differs between studies. From early on, two TBF formats have been evaluated. The clinic-based treatment typically consists of 10–12 TBF

⁴Unlike the traditional approach comparing a treatment group and a control group ("between-group" *ES*), an *ES* can also be derived from pre- to posttreatment changes within a treatment or control group ("within-group" *ES*; e.g., Kraemer & Andrew, 1982). Because of computational differences, Cohen's rule of thumb for small (0.2 < ES < 0.5), medium (0.5 < ES < 0.8), and large between-group *ES* (>0.8) cannot be used for interpreting within-group *ES*s (Cohen, 1987). According to a study comparing different between-group and within-group approaches to derive an *ES*, a within-group *ES* greater than 1 reflects a medium-to-large effect (Hartmann & Herzog, 1995).

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	Study design	Treatment	Patients	Treatment outcome ^a	Long-term follow-up ^b
Thermal biofeedback Andrasik et al. (1984)	Randomized wait list control: TBF vs. PMR vs. wait list	TBF: 10 sessions over 8 weeks; PMR: 10 sessions over 8 weeks	TBF: $N = 14$, PMR: $N = 16$, wait list: $N = 18$; age range: $8-17$ years	<i>TBF:</i> $N = 12$ succ. (85.7%); ES = 3.22; <i>PMR:</i> $N = 10succ. (71.4%); ES = 1.72;wait list: N = 4 succ.(22.2%), ES = 0.71;outcome variable: HAindex$	6-month FU suggests maintenance of treatment outcome
Labbé and Williamson (1984)	Randomized wait list control: TBF vs. wait list	10 sessions of TFB (15-min adaptation + BL, 5-min self-control, 15-min BFB, 5-min self-control) <i>Note. N</i> = 10 of the wait list controls received TBF subsequent to the waiting period	TBF: $N = 14$ (7 M/7 F; mean age = 10.6 years, age range: 7–14 years); <i>wait</i> <i>list:</i> N = 14 (7 M/7 F; mean age: 10.8 years, age range: 7–16 years)	<i>TBF:</i> $N = 13$ succ. (92.8%), <i>ES</i> = 4.74; <i>wait list:</i> $N = 1$ succ. (0.7%), <i>ES</i> = 0.37; outcome variable: HA index	6-month FU (data available for N = 13 of all N = 24 treated patients): $N = 8$ succ. (61.5%), ES = 1.65
Burke and Andrasik (1989)	Multiple baseline: TBF only	Clinic-based TBF: 10 sessions (20-min actual TBF) over 8 weeks and regular home practice; <i>child-</i> <i>or parent-administered home-</i> <i>based TBF</i> : 3 sessions with therapist, 7 manual-guided home sessions (administered by child or parent), regular home practice	Clinic-based TBF: $N = 3$ (3 M; mean age = 11 years); child-administered TBF: $N = 3$ (2 M/1 F; mean age = 12.6 years); parent-administered TBF: N = 3 (1 M/2 F; mean age = 10.6 years); age range: 9–14 years); age	Total $N = 7$ suce. (77.8%); overall $ES = +2.30$ <i>Note</i> . Outcome is based on all patients because there were no apparent differences between treatment formats; outcome variable: HA index	6-month FU ($N = 7$); N = 5 succ. (71%); 8-month FU ($N = 8$); $N =$ 7 succ. (87.5%)
Guarnieri and Blanchard (1990)	Multiple baseline: TBF only	Clinic-based TBF: 10 sessions (12-min actual TBF) over 8 weeks, daily home practice (12-15-min); home-based TBF: 4 sessions TBF in clinic over 8 weeks, manuals for home training, daily home practice	N = 17 (6 $M/11$ F; mean age: 10.9 years, age range: 8-16 years); $N = 1dropout, thus N = 8completers per TBF format$	Clinic-based TBF: $N = 5$ succ. (62.5%); home- based TBF: $N = 3$ succ. (37.5%); overall $ES = 1.33$ (Note. There were no significant differences between treatment formats) outcome variable: HA index	4 month FU (N = 5 children): 4 succ. (80%)

Table I. Overview of Treatment Studies Using Biofeedback for Pediatric Migraine

Outcome data refer to8-month and 3.5-year $N = 15$ patients who wereFU data (Kuhn & FU data (Kuhn & compliant with home $N = 15$ patients who wereFU data (Kuhn & Allen, 1993): HApractice and parentalreduction was reduction was guidelines: $N = 13$ succ. $(86.7\%), ES = 3.38;$ 8 months after treatment, but had returned to baseline 3.5 years after the	(13 F; TBF : $N = 10$ succ. (100%) 6-month FU arrs, age AT : $N = 9$ succ. (90%), ($N = 30$); TBF : arrs, age NT : $N = 9$ succ. (90%); ($N = 30$); TBF :) with wait list: 6 succ. (60%); $N = 9$ succ. (90%); outcome variable: HA AT : $N = 10$ succ. frequency $N = 1$ success	mean $N = 22$ succ. (68.8%), $ES =$ (10.0) age 0.89; outcome variable:) HA index	$ \begin{array}{llllllllllllllllllllllllllllllllllll$	2 $TBF + CBT$: $N = 14$ succ.7-month FU (forge = $(45\%), ES = 0.46; wait$ $TBF + CBT$: HAisr: $lisr$: $lisr$: N = 1 succ. (11%),reduction continuedinsr: $lisr$: N = 1 succ. (11%),to improve fromnean age $ES = 0.03;$ outcometo improve fromerange:variable: HA indexend of treatment toFU with a mean
N = 21 (age range $7-12$ years)	Total $N = 30 (17 M)$ mean age = 12 y range: 8–18 years N = 10 per grou	N = 32 (19 M/13 F age = 11.6 years, range: 8–16 years	TBF alone: $N = 13$ mean age = 12.3 TBF with parent i N = 14 (7 M/7 F age = 12 years); range: 7–18 years	TBF + CBT: N = 3 (8 M/24 F, mean . 15.2 years); <i>wait</i> 15.2 years); <i>wait</i> N = 9 (2 M/7 F, . = 14.3 years), ag 12–19 years)
Home-based TBF: 3 clinic sessions (10-min BL, 10-min BFB, 5-min self-control trial) and daily home practice, in Session 2: parental instruction not to reinforce pain behavior	<i>TBF</i> : 10 sessions (15-min BL, 15-min BFB, 5-min self-control) across 7 weeks; <i>AT</i> : 10 sessions	<i>Home-based TBF</i> : 4 sessions (4-min BL, 4-min self-control, 6 × 3-min BFB) across 8 weeks, manual for home sessions and regular home matrice	TBF: 6 sessions (10-min habituation, 2 × 10-min BFB) and daily home practice; <i>parent training</i> : education (1 session) about role of learning factors and pain management guidelines; weekly review of implementation of parent ouidelines	<i>Stress management</i> <i>TBF + CBT</i> : 4 individual TBF <i>sessions</i> (10 min adaptation, self-control, TBF), 4 group CBT sessions (education, RET principles, PMR, AT), daily home practice (2×)
Multiple baseline: TBF only	Randomized group design: TBF vs. AT vs. wait list	Clinical trial: TBF	Randomized group design: TBF with vs. TBF without parent training	gnitive-behavioral pain/. Nonrandomized wait list control: TBF + CBT vs. wait list (<i>Note</i> : Treatment group was first
Allen and McKeen (1991)	Labbé (1995)	Hermann, Blanchard, and Flor (197)	Allen and Shriver (1998)	Biofeedback and co ₁ Osterhaus et al. (1993)

		Table I. ((Continued)		
	Study design	Treatment	Patients	Treatment outcome ^a	Long-term follow- up^b
Sartory, Müller, Metsch, and Pothmann (1998)	Randomized group design: VCT + CBT vs. PMR + CBT vs. Metoprolol	<i>VCT/PMR</i> + <i>CBT</i> : 10 sessions PMR or VCT (VCT: 3 min self-contr., 12 min VCT, 3 min self-contr.) and CBT ("stress management"; McGrath et al., 1992) over 6 weeks; <i>prophylactic med</i> .: Metoprolol	VCT+: N = 15 (8 M/7 F; mean age = 11.8 years); PMR+: N = 15 (9 M/6 F; mean age = 11.4 years); Metoprolol: N = 13 (9 M/4 F; mean age = 10.5 years); R-16 wears	VCT + CBT: $N = 8$ succ. (53.3%), $ES = 0.88$; PMR + CBT; N = 12 succ. (80%); $ES = 1.00$; $Metoproloi$: $N = 5succ. (38.5%), ES = 0.87;outcome variable: HAfrom encore$	8-month FU: VCT + CBT: ES = 0.60 (N = 10); PMR + CBT: ES = 0.46 (N = 11); Metoproloi: ES = 0.24 (N = 6)
<i>EEG-biofeedback</i> Siniatchkin et al. (2000)	Wait list control (randomization?): CNV-BFB vs. wait list	<i>CNV-BFB</i> : 10 sessions (20 trials baseline CNV in standard paradigm; 30 trials CNV increase (+15 transfer trials), 30 trials CNV decrease (+15 transfer trials)	CNV-BFB: N = 10 (8 M/2 F; mean age = 10.5 years); wait list: $N = 10 (8 M/2 F;$ mean age = 11.6 years)	<i>CNV-BFB:</i> $N = 5$ succ. (50%), $ES = 0.97$; wait list: N = 0 succ. (0%), $ES = 0.17$; outcome variable: HA index	I
Thermal biofeedbac Werder and Sargent (1984)	k and EMG-biofeedback Open clinical trial: EMG-BFB + TBF	On the average 7 sessions using EMG-BFB and TBF	N = 19 (12 M/7 F; mean age = 13.6 years, age range: 7–17 years)	N = 18 succ. (94.7%), ES = 5.71; outcome variable: N of HA hours per week	1-year FU: N = 15 succ. (78.9%), ES = 2.74; 2-3-year FU: N = 12 succ.
Fentress, Masek, Mehegan, and Benson (1986)	Randomized wait list control: Relax + TBF + EMG-BFB vs. relaxation vs. wait list	 Relax + BFB: 9 sessions meditative relaxation, during 5 sessions EMG-BFB + TBF; relaxation; 9 sessions meditative relaxation; 1 st session (both conditions): guidelines for parents how not to reinforce pain behavior 	Total $N = 18$ (7 <i>M</i> /11 F, mean age = 10.1 years, age range: 8–12 years); $N = 6$ per group	Relax + BFB: $N = 5$ succ. (83.3%), $ES = 2.30$; relax: N = 5 succ. (83.3%), ES = 2.30; wait list: $N = 2succ. (41.7%), ES = 1.03$	(63.1%); $ES = 1.85$ 1-year FU ($N = 5$ per treatment group): no significant change in HA activity from end of treatment to FU suggesting the maintenance of the treatment effects

Multiple baseline:9 sessions across 11 weeks: frontal $N = 18$ (9 M/9 F; mean age: $N = 16$ succ; $ES = 3.80$;6-month FU (N =EMG-BFB +EMG-BFB (4 min BL, 4 min BFB,10.2 years, age range:outcome variable: HA17): $N = 14$ succ.PMR + operant4 min BL, 4 min BFB,10.2 years, age range:index17): $N = 14$ succ.PMR + operanta min BL, 4 min BFB,7-12 years)index $(82%), ES = 2.88;$ parentsession: guidelines for parents how $7-12$ years) $(N = 17): N = 14$ succ.not to reinforce pain behaviorsnot to reinforce pain behaviors $(N = 17): N =$ Onen clinical trial.8 sessions of FMG-RFB and/or TRF $Total N = 56(N = 29$ $N = 44$ succ (78.66), FS =Onen clinical trial.8 sessions of FMG-RFB and/or TRF $Total N = 56(N = 29$ $N = 44$ succ (78.66), FS =	EMG-BFB daily relaxation (PMR or migraine, N = 27 mixed 2.67; outcome variable:
Mehegan, Multiple baseline: Masek, EMG-BFB + Harrison, PMR + operant Russo, and parent Leviton education (1987) Onen clinical trial: Womack Smith Onen clinical trial:	and Chen EMG-BFB

vasoconstriction training; FU = follow-up; HA = headache.

 a If possible, two indices of treatment outcome were obtained: Number of treatment successes (succ.) defined as a reduction of HA activity of at least 50% and within-group effect size (ES) based on the pre- to postchange in headache activity. If the standard deviation for the within-group change was not provided, it was estimated based on the pooled standard

deviations for the time points included in the comparison. ^bIf sufficiently detailed information was provided, number of treatment successes and effect size are indicated. If follow-up data were not available for all treatment completers, the number of patients included in the follow-up is given in parentheses.

sessions that are administered by a trained clinician (e.g., Labbé & Williamson, 1984). In the home-based format the children typically receive about three therapist-guided BFB sessions, the remaining treatment program includes self-administered, manual-guided home sessions and home practice (e.g., Allen & McKeen, 1991; Burke & Andrasik, 1989). Although the direct comparison between clinic- and home-based TBF formats (Guarnieri & Blanchard, 1990) has failed to show a reliable difference in efficacy, probably because of a lack of statistical power, home-based TBF tends to yield less improvement than does therapistadministered TBF. This situation probably accounts substantially for the heterogeneity of TBF efficacy across studies. For example, in the Hermann et al. (1997) study, which involved the largest sample of pediatric migraineurs treated in a home-based TBF format, approximately 69% of the children were clinically improved as compared to success rates of up to 100% that have been obtained for clinician-administered TBF (e.g., Andrasik et al., 1984; Labbé, 1995; Labbé & Williamson, 1984). At this point, little is known about why home-based TBF as compared to clinic-based TBF tends to be less successful. It is certainly not the case that older children are necessarily better suited for receiving home-based TBF (Hermann et al., 1997). One may speculate that clinic sessions guarantee a certain amount of regular TBF practice time, whereas actual practice time is hard to control in a home-based treatment format. Moreover, children may more easily acquire a sense of self-control when regularly reinforced by a therapist. Also, regular contacts with a therapist could facilitate the transfer of the acquired handwarming skill into daily life by providing contingent feedback to the child about his/her progress. On an individual basis, it is difficult to predict whether home-based TBF or clinician-administered TBF is more successful.

TBF has also been used in combination with EMG-BFB and progressive muscle relaxation (PMR) or cognitive therapy in the treatment of migraine (see Table I). When compared to studies using TBF alone, the combination of TBF and EMG-BFB appears to be at least as efficacious. The only study involving a combination of TBF and CBT (Osterhaus et al., 1993) yielded a lower success rate than did TBF alone that may be partially due to the slightly older patients in this study. Whether EMG-BFB or cognitive therapy adds to the treatment effect above and beyond TBF is unclear, because there are no direct comparisons between TBF and alternative treatments (see also Hermann et al., 1995). A parsimonious interpretation of the outcome data certainly suggests that there is no advantage of adding EMG-BFB or cognitive therapy to TBF. In his review of the adult HA treatment literature, Blanchard (1992) came to a very similar conclusion.

Recently, alternative types of BFB in the treatment of pediatric migraine have been tested. In one study (Sartory et al., 1998), children were taught vasoconstriction of the temporal artery (VCT) by providing feedback of the blood volume pulse amplitude recorded by a photoplethysmographic sensor. Overall, the combination of VCT and stress management was not superior to the combination of PMR and stress management or the prophylactic medication. Although conclusions as to the specific treatment effect of VCT are precluded because of the use of treatment combinations, VCT does not seem to provide an advantage. Again, such a conclusion would be consistent with the adult treatment literature. As Blanchard (1992) pointed out, the specific efficacy of VCT in migraine remains to be demonstrated given the paucity of controlled studies with sufficient sample sizes.

A new BFB approach was evaluated by Siniatchkin et al. (2000). On the basis of findings that migraine is associated with cortical hyperexcitability (e.g., Kropp & Gerber, 1993; Welch, 1998), they trained children suffering from migraine to control the contingent

negative variation (CNV). The CNV is a slow cortical potential that is observed after a warning stimulus when a participant is awaiting an imperative stimulus to perform a response such as pressing a key as fast as possible (for a review, see Birbaumer, Elbert, Canavan, & Rockstroh, 1990). Because slow cortical potentials are presumed to reflect cortical excitability, learning how to self-regulate the CNV may enable the individual to prevent migraine attacks. CNV-BFB has been shown as a promising approach to treat drugrefractory epilepsy by voluntarily reducing the cortical excitation threshold (Kotchoubey, Blankenhorn, Froscher, Strehl, & Birbaumer, 1997). In the study by Siniatchkin et al. (2000), CNV-BFB yielded a moderate success rate of 50%, but was superior to a wait list control. Because of the limited sample size and the lack of other studies, conclusions as to the efficacy of CNV-BFB are not possible at this point. Because BFB of slow cortical potentials requires sophisticated BFB equipment, TBF should remain the treatment of choice until the superiority of CNV-BFB over TBF is demonstrated.

Maintenance

A number of the TBF (alone or combined with EMG-BFB or CBT) treatment studies provide follow-up data for periods of 6 months up to 1 year. Even if there may be a selfselection bias due to the attrition of some of the treatment completers, the data suggest a satisfactory maintenance of the treatment gains, at least for this intermediate time range (see Table I). Yet, given the very limited data on the natural course of pediatric migraine, nonspecific factors such as "simply growing out of the pain problem" cannot be completely ruled out (cf. Hernandez-Latorre & Roig, 2000).

Tension Headache

Contrary to pediatric migraine, few studies have evaluated psychological interventions (BFB or other treatment modalities) for tension HA in children. This may reflect a lesser request for treatment because of a relative infrequency of tension HA or because of other factors influencing treatment participation. Although tension HA is certainly not uncommon in children, the actual prevalence has yet to be determined (see above; Labbé, 1988). Tension HA seems to be more prevalent among adolescents aged 14–15 and above. Not surprisingly, most of the available psychological intervention studies for adolescent tension HA sufferers are therefore school-based relaxation trainings designed for adolescents 14 and above (e.g., Larsson, Melin, & Döberl, 1990). It is also possible that parents and children are less concerned about tension HA may be more variable and include longer intervals of HA remission, again making requests for treatment less likely.

Mirroring the adult treatment literature, EMG-BFB from the m. frontralis has been the BFB modality of choice in the treatment of tension HA in children. Aside from case reports (Andrasik, Blanchard, Edlund, & Attanasio, 1983; Labbé & Ward, 1990), few larger scale or even controlled studies are available that have evaluated the effectiveness of EMG-BFB. If treatment outcome is compared across the three available studies (see Table II), EMG-BFB alone seems to yield remarkably consistent success rates of about 80–90% and an *ES* of about 1.5. Although the *ES* and success rates reported by Kröner-Herwig et al. (1998)

	Study design	Treatment	Patients	Treatment outcome a	Long-term follow- up^b
EMG-biofeedback Grazzi, Leone, Frediani, and Bussone	Multiple baseline EMG-BFB	24 sessions EMG-BFB (M. frontalis) over 12 weeks (10-min BL, 10-min BFB, 10-min BL), home macrice of self-reonlarion skills	N = 10 (5 M/5 F, mean age = 12.8 years, age rance: 12-15 years)	N = 9 succ. (90%), $ES = 1.52$; outcome variable: HA index	1-year FU: $N = 10$ succ. (100%), $ES = 1.69$
Kröner-Herwig, Plump, and Pothmann (1992)	Nonrandomized group design: EMG-BFB vs. PMR	EMG-BFB (M. frontalis): 12–30-min sessions over 6 weeks (3-min BL, self-control; 10-min BFB, self-control; 10-min BFB,	EMG-BFB: $N = 8$ (3 M/5 F, mean age = 10.6 years, age range	<i>EMG-BFB: ES</i> = 1.54; <i>PMR:</i> <i>ES</i> = 1.48; outcome variable: HA frequency	6-month FU: <i>EMG-BFB</i> : ES = 1.33 ($N = 8$); <i>PMR</i> : ES = 1.47 ($N = 7$)
		self-regulation skill; <i>PMR</i> : 6 weekly 1-h sessions and home	8-14 years); <i>PMR</i> : N = 8 (4 M/4 F,		
		practice	mean age = 11.6 years, age range: 9–14 years) Note N – 7 mixed		
			HA patients in each		
Kröner-Herwig,	Randomized wait	EMG-BFB (M. frontalis): 12–30-min	Total $N = 50$	EMG-BFB alone: $N = 8$ succ.	6-month FU: EMG-BFB
Mohn, and Pothmann	list control: EMG-BFB	sessions (6–9 min BFB, $2-3 \times 2$ -min self-control trials);	(20 M/30 F, mean) age = 10.96 years,	(80%), ES = 1.41; EMG-BFB with parent involvement: N = 6 succ.	alone: $N = 9$ succ. (90%), ES = 2.07; EMG-BFB with
(1998)	with/without	<i>PMR</i> : 6 sessions, audio cassette	age range:	(60%), ES = 0.58; PMR alone: $M = A concert (A002) ES = 0.18$.	parent involvement: $N = 7000 \text{ JPS} - 1000$
	parental involvement vs.	ion noune practice, parental involvement: 3 sessions	o-14 years) with a diagnosis of tension	PMR with parent involvement:	PMR alone: $N = 5$ succ.
	PMR	(education, parental guidelines	or mixed HA;	N = 7 succ. (70%), $ES = 0.52$;	(50%), ES = 0.63; PMR
	with/without parental	how not to reinforce pain behavior, review of implementation)	N = 10 per group	wait list: $N = 4$ succ. (40%), ES = 0.25; outcome variable: HA	with parent involvement: $N = 5$ succ. (50%),
	involvement vs. wait list			frequency	ES = 0.55

Table II. Overview of Biofeedback Treatment for Tension and Mixed Headache in Children and Adolescents

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iofeedback-assis	ted relaxation Pandomized	$EMC-BEB (M from fields) \perp DMP$.	$EMC_{RER} \perp DMP$	$EMG_{\rm BEB} \pm {\rm DMP} \cdot \max$	3-month FILEMC_RER 1
Grazzi.	placebo-	initially 4–20-min sessions PMR.	N = 20	reduction: 54.2% , $ES = 0.9$:	<i>PMR</i> : mean HA red.:
D'Amico,	control:	then 6-21-min sessions BFB	(10 M/10 F), mean	Placebo: mean HA reduction:	58.2%, ES = 0.83;
Leone, and	EMG-BFB +	(7-min baseline, 7-min BFB,	age = 11.1 years,	56.5%, $ES = 1.0$; outcome	3-month FU-Placebo:
Andrasik	PMR vs.	7-min self-control); Placebo: 10	<i>Placebo</i> : $N = 10$	variable: HA index	mean HA red.: 63.7%,
(1998)	placebo	sessions, EMG was recorded while	(5 M/5F), mean		ES = 1.16; 6-month
		participants sat calmly and tried to	age = 13 years;		FU-EMG-BFB + PMR:
		relax on their own, no feedback	all patients:		mean HA red.: 75.9%,
		was provided; in both conditions:	IHS-diagnosis of		ES = 1.36; 6-month
		2 sessions per week	episodic tension		<i>FU-Placebo</i> : mean HA
			HA; age range:		red.: 63.3% , $ES = 1.14$;
			11-15 years; during		1-year FU-EMG-BFB +
			baseline: sign.		<i>PMR</i> : mean HA red.:
			higher HA activity		86.0%, ES = 1.59; I-year
			in the placebo		FU-Placebo: mean HA
			group		red.: 60.0% , $ES = 0.95$
Grazzi et al.	Open clinical trial:	EMG-BFB (M. frontalis) + PMR:	N = 38 completers	Mean HA index ^{c,d} : pre: $M = 155.95$	I-year FU (mean HA index):
(2001)	EMG-BFB +	initially 4–20-min sessions PMR,	(16 M/22 F), age	(SD = 26.7), post: $M = 52.7$	$M = 41.91 \ (SD = 15.7)$
	PMR	then 6-21-min sessions BFB	range: 7–17 years;	(SD = 10.48); there was a	3-years FU (mean HA
		(7-min baseline, 7-min BFB,	all patients:	significant reduction in HA	index) $M = 8.56$
		7-min self-control)	episodic tension	activity from pre- to posttreatment;	(SD = 6.86); there was a
			HA; $N = 6$	outcome variable: HA index	significant further HA
			dropouts (2 M/4 F);		reduction from the 1-year
			N = 10 (3 M/7 F):		up to the 3-years FU
			3 years FU data not		
			available		

Note. The effect size (E3) for long-term follow-up data was only computed if the same outcome variable (e.g., HA frequency) was used as for the pre-post comparison, and if the provided outcome data were of the same nature (e.g., mean/standard deviation, p value, etc.) as the pre-post outcome data. EMG-BFB = EMG-biofeedback; ES = effect size; HA = headache; PMR = progressive muscle relaxation.

^a If possible, 2 indices of treatment outcome were obtained: Number of treatment successes (succ.) defined as a reduction of HA activity of at least 50% and within-group effect size (ES) based on the pre- to post-change in headache activity. If the standard deviation for the within-group change was not provided, it was estimated based on the pooled standard deviations for the time points included in the comparison.

²If sufficiently detailed information was provided, number of treatment successes and ES are indicated. If follow-up data were not available for all treatment completers, the number of patients included in the follow-up is given in parentheses.

^{dT}The number of treatment successes was not provided.

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suggest differential effectiveness of EMG-BFB with or without parental involvement in comparison to PMR and the wait list controls, these differences failed to reach statistical significance, most likely due to the limited power (cell size of 10). In light of the large variation in treatment outcome for PMR in the studies by Kröner-Herwig et al., the superiority of EMG-BFB over alternative treatments such as PMR awaits further investigation. Unlike EMG-BFB alone, the combination of EMG-BFB and PMR has recently been evaluated against a placebo condition (Bussone et al., 1998). Both BFB-assisted PMR and the relaxation placebo were found to be equally effective up to 6 months after the end of treatment, whereas BFB-assisted relaxation was found to be superior at longer follow-up intervals because of a continued improvement in the treatment group. It is certainly noteworthy that the children in the placebo condition maintained the substantial reduction in HA activity from the end of treatment throughout the follow-up period.

If the criteria proposed by the Task Force on Promotion and Dissemination of Psychological Procedures (1995) are applied rather leniently, EMG-BFB alone can be considered as a promising intervention for pediatric tension HA. However, a caveat is warranted. Both studies by the Kröner-Herwig group included children suffering from tension HAs as well as children suffering from mixed (both tension and migraine HA symptoms) HA, but did not test for differences in treatment outcome depending on HA diagnosis. BFB-assisted PMR also seems to be a promising treatment approach. Yet, the specific contribution of EMG-BFB versus relaxation to treatment outcome needs to determined, especially because the *ES* obtained for this treatment combination seems to be somewhat lower than that for EMG-BFB alone.

Maintenance

All three studies on EMG-BFB for pediatric tension HA have provided 6-month or 1-year follow-up data. Overall, the reduction in HA activity was maintained (e.g., Kröner-Herwig et al., 1992) or improved even further throughout the follow-up period (Grazzi et al., 1990; Kröner-Herwig et al., 1998). Similar results were obtained for BFB-assisted relaxation (Bussone et al., 1998; Grazzi et al., 2001). Grazzi et al. (2001) even reported continued improvement from the 1-year up to the 3-year follow-up. Although these findings suggest a very favorable maintenance of treatment gains, the same limitations apply as for the migraine treatment studies. In fact, one may even speculate that spontaneous remissions of tension HA (e.g., due to stress relief associated with a change of school) are more likely to occur than in migraine. In this regard, it is certainly noteworthy that the placebo condition in the Bussone et al. (1998) study yielded an average reduction in HA activity by more than 50% (*ES* = 1) that was maintained throughout the 1-year follow-up period.

Other Childhood Pain Problems

Despite the fact that children also suffer from recurrent or chronic pain other than HAs, the merit of BFB in treating other pain problems has rarely (e.g., rheumatoid arthritis, sickle cell disease), if at all (e.g., recurrent abdominal pain, cancer-related pain), been investigated. One reason for the paucity of treatment trials may be that the physiological response that should be changed in the desired direction seems less clear in the case of disease-related pains (e.g., rheumatoid arthritis, cancer) or, specifically, in the case of recurrent abdominal pain. Hence, BFB (TBF or EMG-BFB from the frontalis muscles) has been used mostly as a relaxation method and, as such, may not necessarily be superior over other relaxation procedures such as PMR. Lavigne, Ross, Berry, Hayford, and Pachman (1992) reported moderate levels of pain relief in eight children suffering from juvenile arthritis who had been treated with a treatment package consisting of PMR, EMG-BFB, and TBF (two sessions each) and a parental pain management training. In eight children and adolescents (10–20 years) suffering from sickle cell disease, BFB-assisted relaxation (six sessions EMG-BFB and TBF) was found to significantly reduce perceived pain and frequency of self-treated pain episodes, but did not change the number of pain crises treated in the hospital (Cozzi, Tryon, & Sedlacek, 1987). If psychological factors such as perceived self-efficacy are crucial for mediating the success of BFB (see below), a stronger emphasis on the aspect of self-control rather than on relaxation could improve BFB efficacy and may make BFB an interesting treatment option also for childhood pain other than HA.

TREATMENT MECHANISMS OF BIOFEEDBACK

Placebo Response

Obviously, one of the first questions to ask is whether the treatment effects are due to nonspecific effects such as expectation of improvement, the instillation of "hope" or to a placebo effect. If it is true that children have more confidence in special abilities including psychophysiological self-regulation skills (e.g., Attanasio et al., 1985), children may be even more prone to a placebo effect than are adults. Unfortunately, with the exception of BFB-assisted relaxation (Bussone et al., 1998), none of the BFB procedures for any of the childhood pain problems has been compared directly to a credible placebo condition. Thus far, there is only indirect evidence that BFB is superior to placebo, at least for pediatric migraine. In our 1995 meta-analytic review (Hermann et al., 1995), we obtained an average ES of 0.56 for psychological placebo conditions based on a sample of four studies. The average ES for TBF alone or combined with EMG-BFB (both ES > 2.5) was significantly higher suggesting an effectiveness greater than placebo. If it is assumed that placebo treatments yield effects of similar magnitude irrespective of HA type, EMG-BFB for tension HA may be more effective than placebo. As shown by Bussone et al. (1998), BFB-assisted relaxation is superior to placebo in the treatment of pediatric tension HA, at least in the long run. Nonetheless, the sizable placebo effect (ES = 1) that was observed in the same study even at the 1-year follow-up clearly emphasizes the need to further elucidate the role of placebo effects in mediating treatment success of BFB. Strictly based on the empirical literature available at this point in time, placebo effects cannot be ruled out in mediating BFB treatment effects for childhood HA and for childhood pain in general.

Mediating Mechanisms

The success of BFB has been attributed to physiological and/or psychological factors. Physiological accounts are based on the assumption that a dysregulation of specific physiological processes (e.g., elevated muscle tension) underlies the pain problem. Hence, learned control of the relevant physiological process should lead to a corresponding pain relief. Yet, studies with adult HA sufferers have found little or no association between BFB performance and amount of HA relief (for a review, see Blanchard, 1992). In children, few studies have specifically tested this relationship. For CNV-BFB, no correlation between the acquired CNV self-control and the reduction of HA activity was found (Siniatchkin et al., 2000). Similarly, an analysis of the data on percent HA improvement and percent change in EMG activity provided for each participant in the Grazzi et al. (1990) study does not reveal a significant correlation (r = .11) between BFB performance and treatment outcome in tension HA participants. Moreover, in the Bussone et al. (1998) study, BFB-assisted PMR did not yield significant changes in EMG resting levels despite the change in HA activity. By contrast, Allen and McKeen (1991) reported a correlation of .85 between HA relief and the extent to which the children's handwarming skills improved. The internal validity of the obtained measure to represent acquisition of handwarming ability was demonstrated. Osterhaus et al. (1993) found a significant correlation of .42 only between the rise in finger temperature during the last session and pre- to postchange in HA frequency (but not for other HA outcome measures).

Taken together, these findings do not provide strong evidence for a purely physiological model of BFB success. Thus far, a strict evaluation of this model (both in adults and in children) has been impeded by the difficulty in specifying the type and magnitude of dysregulation (e.g., elevated baseline levels, enhanced stress reactivity) that presumably contributes to the pain problem (Flor & Turk, 1989) and, by consequence, to clearly define criteria on how to operationalize "acquired physiological control."

Psychological factors such as perceived self-efficacy or perceived control have also been put forth as the basis of the efficacy of BFB. In a recent study, six children suffering from migraine were treated with TBF (Allen & Shriver, 1997). Initially, they received performance feedback indicating moderate success. When HA activity had reached a stable level, high success feedback was provided that suggested a marked increase in handwarming skills relative to peers even when there was no actual improvement. In four of the patients, high success feedback was associated with a marked reduction in HA activity that occurred regardless of the actual BFB performance. These preliminary findings support the importance of cognitive processes such as perceived self-control and possibly self-efficacy as a mediating mechanism and are consistent with findings in adult HA sufferers (Blanchard et al., 1994; Holroyd et al., 1984). Clearly, at this point in time, the available data do not allow us to determine the relative importance of physiological or psychological factors in mediating BFB treatment outcome. If the success of BFB is mediated largely by psychological mechanisms, BFB may prove to be useful in the treatment of a variety of childhood pain problems (e.g., RAP), even if the specific contribution of muscle tension or other possibly dysregulated physiological processes is not fully understood.

Predictors of Treatment Outcome

Few efforts have been made to identify variables that may predict treatment outcome. Procedure-related aspects such as home practice have been shown to predict treatment success (Allen & McKeen, 1991) or were unrelated to it (Hermann et al., 1997). Similarly, the specific importance of psychosocial, pain-related, and background variables is unclear. Osterhaus et al. (1993) determined that girls with a shorter history of migraine experienced the greatest reduction in HA frequency in response to their treatment package including TBF

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and stress management techniques. Hermann et al. (1997) found that the younger the child, the higher the initial level of psychosomatic symptoms and the greater the externalizing behavior tendencies (e.g., acting out, difficulty with impulse control), the greater was the HA relief due to a home-based TBF treatment. No significant relationship between treatment success and the child's sex and HA chronicity was observed. Because of differences in the provided treatment (i.e., CBT + TBF vs. home-based TBF) and with regard to the treated sample of patients (i.e., mean age, age range, sex proportion), the results cannot be directly compared. In light of the sex-specific and probably hormonally mediated change in migraine prevalence between the ages of 12 and 18 (e.g., Linet & Stewart, 1984) and the age-related increase in reported stress (Compas, Davis, & Forsythe, 1985), it seems plausible to assume that outcome predictors may differ in type (e.g., age, sex, emotional adjustment, family environment, treatment format) and relative importance between pre-adolescent and adolescent migraineurs. Whether this hypothesis holds true not only for migraine but also for other types of recurrent childhood pain remains to be demonstrated.

Role of Operant Factors

On the basis of the importance of social reinforcement for the maintenance of pain (e.g., Fordyce, 1976; Rachlin, 1985), attempts have been made to enhance the efficacy of BFB in the treatment of childhood HAs by adding a behavioral pain management training for parents. Although this combination may appear somewhat unusual, given that an individual's self-regulatory abilities constitute the core rationale underlying BFB, it has been argued early on that BFB is only useful under the condition (among others) that positive or negative reinforcement is not involved in symptom maintenance (Miller & Dworkin, 1977). The parental training typically comprises pain management guidelines that aim to minimize positively (e.g., paying attention) or negatively reinforcing (e.g., excuse from daily chores) parental responses to the child's pain behaviors. Moreover, the parents are taught to encourage their children to practice and use their self-regulation skills and to maintain normal daily activities during pain episodes. Thus far, results have been mixed. Allen and Shriver (1998) found that TBF combined with a parent pain management training yielded greater HA relief in pediatric migraineurs than did TBF alone, thus suggesting a beneficial effect of the added parental training. Furthermore, the parents in both groups significantly decreased their maladaptive responses to the child's pain. This decrease was especially pronounced if the parents had received pain management training. Nonetheless, the observed difference in treatment outcome between the two TBF conditions could also be accounted for by the unusually small treatment effect of the TBF alone condition if compared to other TBF studies including previous studies by the same authors.

Kröner-Herwig et al. (1998) reported that the addition of parent training did not significantly influence the outcome of a EMG-BFB or PMR treatment. If the *ESs* are considered, however, the parent training seems to have an opposite effect depending on the type of treatment: Children treated with EMG-BFB benefited less from treatment if their parents were involved, whereas children treated with PMR improved more. Whether parents engaged in maladaptive responses prior to treatment, and whether the parental training was successful in modifying the parental responses, was not assessed in this study. Hence, it is not clear whether the two groups were comparable with regard to the level of maladaptive

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parent responses before treatment, and whether the parent training had similar effects in both groups.

Undoubtedly, efforts to bolster the effectiveness of BFB interventions by adding operant therapy components are worthwhile. However, to determine the specific contribution and advantage of an added operant parent training, the extent of maladaptive parental responses to children's pain at pretreatment and treatment-induced changes in those parental responses needs to be investigated in sufficient detail.

CHILD-RELATED ISSUES OF BFB TREATMENT

Motivation and Learning Success

For a variety of reasons, children have been considered as prime candidates for BFB. On the basis of clinical observations, Attanasio et al. (1985) have argued that children are more enthusiastic and less skeptical, have more psychophysiological ability, learn more quickly, and experience fewer failures with treatment (see also Culbert et al., 1996). Because motivation for and acceptance of BFB (and their impact on treatment outcome) have not been directly assessed in children, it is not clear whether such descriptions primarily reflect clinicians' (and researchers') impressions and beliefs. The purportedly greater enthusiasm and faster learning rate of children has been forwarded to explain the widely held belief that children are better at acquiring BFB skills. Suter and Loughry-Machado (1981) have reported that (healthy) children as compared to adults were better at controlling their skin temperature with the latter group failing to acquire any skin temperature control. In a subsequent study, however, these findings could not be replicated (Suter, Fredericson, & Portuesi, 1983). Furthermore, a recent archival analysis of TBF and EMG-BFB data obtained from a selected sample of treatment studies for HA in adults and children failed to find evidence for children's superiority over adults in acquiring self-regulation skills (Sarafino & Goehring, 2000). Even if the limited database is taken into account, there is considerable reason to believe that children and adults do not differ significantly in their ability to learn how to self-control psychophysiological responses.

Treatment Success

Unlike the acquisition of BFB control, the archival analysis by Sarafino and Goehring (2000) corroborated that, in fact, children suffering from HAs benefit significantly more from BFB than do adults. On the basis of the analysis of a total of 6 versus 15 TBF studies including children or adults, respectively, children achieved a mean HA reduction of 62.3% as compared to 33.9% in adults. EMG-BFB led to an average HA relief of 80.8% in children (4 studies) versus 48% in adults (25 studies). The reasons for this substantial difference in treatment outcome between children and adults are less clear. As Sarafino and Goehring (2000) showed, methodological aspects such as differences in the accuracy of the children's versus adults' HA diaries or the added relaxation training in many of the child treatment studies cannot fully explain this difference in treatment success. Aside from age-related differences in motivation and outcome expectation, the chronicity and severity of the pain problem together with the accompanying increased psychological distress and prolonged use of medication may explain the greater refractoriness of HAs to BFB in adults. Children suffering from recurrent pain are not particularly prone to clinically relevant levels

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of anxiety or depression (e.g., Hermann et al., 1997; Walker, Garber, & Greene, 1993), whereas depression and anxiety problems are highly common among adult pain patients and probably reflect the psychological consequences of prolonged living with pain (e.g., Banks & Kerns, 1996; Holroyd et al., 2000; Marcus, 2000).

Early Treatment as a Secondary Prevention

As mentioned above, BFB (and other psychological treatments) for childhood pain may not only be indicated as a primary intervention but may also hold promise to reduce the risk of pain chronicity and pain-related emotional sequelae. Yet, despite its appeal, there is little empirical evidence to support this hypothesis. Kuhn and Allen (1993) collected longer term (3.5 years) follow-up data for 18 of the 21 children suffering from migraine in their original study (Allen & McKeen, 1991). Although treatment success had been maintained at the 8-month follow-up, HA activity had returned to baseline levels more than 3 years after treatment. This return to baseline was observed both in noncompliant children who had initially experienced little reduction of HA activity and in children who had been compliant and had been clinically improved. Moreover, at the 3.5-year follow-up, there was no difference in HA activity between children who had undergone treatment and a group of five children who had dropped out from the original study before receiving treatment. A more favorable long-term outcome was reported by Grazzi et al. (2001). A total of 92% of their sample of children suffering from episodic tension HAs who had received BFBassisted relaxation training were clinically improved 3 years after the end of treatment. However, no control group was included, thus making it impossible to determine whether this improvement was primarily due to treatment or reflects the natural course of episodic tension HA in children. These data clearly caution against too much optimism regarding long-term treatment benefits in children receiving BFB for recurrent pain. Whether booster sessions may be helpful to stabilize treatment success has not been investigated.

SUMMARY AND CONCLUSION

Consistent with the available empirical literature, our review on the use of BFB in the treatment of childhood pain has focused mainly on childhood HA. TBF is probably efficacious in the treatment of pediatric migraine, and EMG-BFB is a promising treatment approach for tension HA in children, whereas the usefulness of BFB in the treatment of other childhood pain problems such as RAP or rheumatoid arthritis has not been demonstrated. In recent years, BFB protocols have increasingly been combined with other interventions such as parental pain management, thus obscuring BFB-specific treatment effects. As it has been hypothesized by clinicians early on, children suffering from HAs benefit significantly more from BFB than do adults. However, the higher treatment success is not accounted for by a better BFB performance in children. Overall, little research has been done to determine the relative importance of physiological (i.e., BFB performance) and psychological (e.g., selfefficacy, outcome expectation) factors in mediating the treatment effect of BFB in children.

In our opinion, there are three promising avenues for future research on the use of BFB in the treatment of childhood HAs and other pain problems. First, placebo-controlled studies are necessary to demonstrate the superiority of BFB over placebo. This is especially warranted because children may be more prone to placebo effects possibly because of their

greater enthusiasm and belief in treatment success. Second, more efforts should be made to identify mediating mechanisms (i.e., physiological vs. psychological) and outcome predictors. For example, if outcome predictors are shown to be age-dependent, treatment efficacy could be further enhanced by tailoring age-specific BFB protocols. Third, research should focus more on systematically demonstrating that BFB efficacy can (or cannot) be enhanced by additional treatment components such as parental pain management training rather than evaluating treatment packages that do not allow one to disentangle which intervention works or is redundant.

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