



Efficacy of biofeedback for migraine: A meta-analysis

Yvonne Nestoriuc^{*}, Alexandra Martin

Philipps-University of Marburg, Section for Clinical Psychology and Psychotherapy, Gutenbergstr. 18, 35032 Marburg, Germany

Received 16 June 2006; received in revised form 10 August 2006; accepted 5 September 2006

Abstract

In this article, we meta-analytically examined the efficacy of biofeedback (BFB) in treating migraine. A computerized literature search of the databases Medline, PsycInfo, Psycdex and the Cochrane library, enhanced by a hand search, identified 86 outcome studies. A total of 55 studies, including randomized controlled trials as well as pre–post trials, met our inclusion criteria and were integrated. A medium effect size ($\bar{d} = 0.58$, 95% CI = 0.52, 0.64) resulted for all BFB interventions and proved stable over an average follow-up phase of 17 months. Also, BFB was more effective than control conditions. Frequency of migraine attacks and perceived self-efficacy demonstrated the strongest improvements. Blood-volume-pulse feedback yielded higher effect sizes than peripheral skin temperature feedback and electromyography feedback. Moderator analyses revealed BFB in combination with home training to be more effective than therapies without home training. The influence of the meta-analytical methods on the effect sizes was systematically explored and the results proved to be robust across different methods of effect size calculation. Furthermore, there was no substantial relation between the validity of the integrated studies and the direct treatment effects. Finally, an intention-to-treat analysis showed that the treatment effects remained stable, even when drop-outs were considered as nonresponders. © 2006 International Association for the Study of Pain. Published by Elsevier B.V. All rights reserved.

Keywords: Migraine; Biofeedback; Behavioral therapy; Meta-analysis

1. Introduction

Migraine is a highly prevalent disease affecting individuals, their families, and economies across the world (Lipton et al., 2003). The highest prevalence rates have been reported in North America where 18% of the women and 7% of the men experience one or more migraine attacks per year (Lipton et al., 2001), but figures from Europe are similar (Stovner et al., 2006). Although effective drugs for migraine treatment exist (Oldman et al., 2002), they are not available to a substantial portion of patients due to medical contraindications (e.g., poor tolerance, pregnancy). In addition,

long-term prevention through prophylactic medication is a major problem (Yoon et al., 2005). Confronted with such limitations of drug treatments patients and health care providers consider behavioral treatments as an alternative or an addition to pharmacological treatments.

Biofeedback (BFB) is one of the most prominent behavioral approaches to pain management. In BFB patients learn voluntary control over their bodily reactions through the feedback of physiological processes. The most frequently used BFB modalities for migraine treatment are peripheral skin temperature feedback (TEMP-FB), blood-volume-pulse feedback (BVP-FB) and electromyography feedback (EMG-FB). Previous meta-analytic reviews of behavioral migraine treatments have consistently shown BFB to be effective, with average improvement rates around 40% (Blanchard et al., 1980; Penzien et al., 1985; Blanchard and Andrasik,

^{*} Corresponding author. Tel.: +49 6421 2823646; fax.: +49 6421 2828904.

E-mail address: yvonne.nestoriuc@staff.uni-marburg.de (Y. Nestoriuc).

1987) and with clinical reductions of migraine activity equalling those of pharmacotherapies (Holroyd and Penzien, 1990). More recently, Goslin et al. (1999) extended prior meta-analytical work by integrating standardized effect sizes instead of percentage improvement scores. They reported medium effect sizes for EMG-FB and TEMP-FB in combination with relaxation. Confidence intervals for these effects were rather broad, since the analyses were based on only 11 studies. Also, BVP-FB was explicitly excluded, because the authors considered it a non-standard and technically difficult BFB technique. However, most of the current multichannel BFB-systems provide BVP-FB and some quite promising results have already been reported (Kropp et al., 1997). Thus, in order to draw firm conclusions concerning the efficacy of BVP-FB further meta-analyses are needed. Likewise, the potential of BFB for long-term migraine prevention has not yet been meta-analytically demonstrated (see Blanchard, 1987, for some tentative evidence).

Apart from evaluating the long-term outcome of BFB and the outcome of BVP-FB, the present meta-analysis includes the following significant improvements: First, it offers a comprehensive quantitative summary of 55 studies, including randomized controlled trials (RCTs) as well as pre–post trials. Second, the inclusion of a larger number of studies provides the opportunity to evaluate different feedback modalities and outcome variables, to identify subgroups of responders and to control for methodological variation across the studies with moderator analyses. Finally, several sensitivity analyses are performed to evaluate the robustness of the results and conclusions, including the analysis of publication bias, intention-to-treat analysis and comparisons among different methods of effect size calculation.

In sum, the present meta-analysis does not only offer more precise estimates of general BFB efficacy, but also provides first meta-analytical results concerning the long-term outcome of BFB, the outcome of BVP-FB, and potential predictors of treatment outcome.

2. Method

2.1. Search procedure

An extensive literature search was conducted electronically across three international and one German database (Medline, PsycInfo, the Cochrane Central Register of Controlled Trials (CENTRAL) and Psynex from the first available year to June 2005) using the search terms *biofeedback* or *behavioral treatment*, paired with either of the terms *migraine*, *vascular headache* or *mixed headache*. Additional studies were identified by manual search in reference lists of previous meta-analyses and primary studies. A priori decisions were made to search only for published work and to control for publication bias

via posteriori analysis. Together these searches generated nearly 800 matches and each of them was examined for relevance to the defined topic.

2.2. Inclusion criteria

Studies were selected for inclusion according to the following criteria: (1) Studies had to evaluate individually administered BFB treatments for adults (TEMP-FB, EMG-FB, BVP-FB or vasoconstriction and dilatation training, galvanic skin response feedback, BFB in combination with other behavioral therapies). (2) Diagnosis had to be made according to a standardized classification system (i.e., *Ad Hoc Classification System*, 1962; IHS, 1988) or an exact description of the disorder including characteristic features of migraine (e.g., severe pain, throbbing character, nausea, phono/photophobia or aura). Double diagnoses of migraine and tension type headache (mixed or combination headache) were included. (3) Treatment outcome had to be measured with standardized headache diaries, pain scales or other psychological questionnaires (e.g., self-efficacy, depression). Studies reporting only physiological parameters were excluded. (4) Follow-up studies of at least six months length were included. In case of multiple follow-up measurements we analysed the data from the longest follow-up phase. (5) Case studies and studies with less than four patients per treatment group were excluded. (6) Studies were required to present sufficient statistical data for the calculation of effect sizes, that is, means and standard deviations, t , F , r or χ^2 statistics, frequencies or probability levels. (7) Only studies published in English or German were included. (8) Double publications were excluded.

A total of 55 studies met inclusion criteria and were included in the meta-analysis. Details of the selection process are shown in Fig. 1.

2.3. Data abstraction and validity assessment

Regarding the methodological quality of the studies, no additional inclusion criteria were applied and RCTs as well as uncontrolled or nonrandomized studies were included. Following the “sensible course” (Glass, 1976), we controlled for possible confounds of effect size, by rating the quality of each study on a validity scale and analysing it as a moderator of the study findings.

For each study, clinical and methodological aspects were coded with a structured coding scheme,¹ including information on report identification, methodology, subjects and treatment (see Appendix). The validity scale consisted of 12 quality related items, including potential biases to pain research reports (Jadad et al., 1996). It was designed to capture threats to internal and external validity, construct validity and statistical conclusion validity (Wortmann, 1994).

The first author and another independent reviewer each coded one-half of the studies. A random sample of $n = 20$ studies was coded by both raters, to evaluate the quality of the coding process. Reliability indices were computed using Cohen’s Kappa for categorical items and intraclass

¹ The full versions of the coding scheme and the validity framework can be requested from the authors.

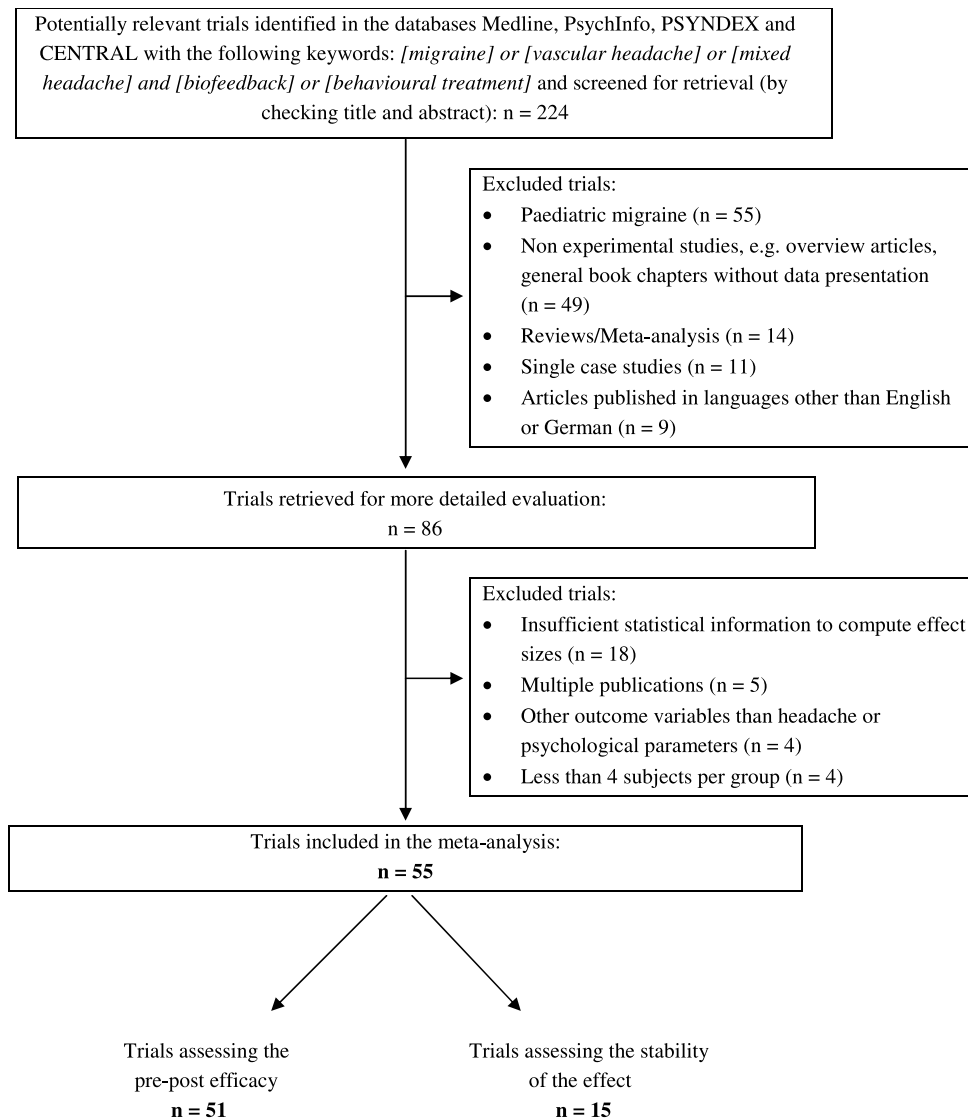


Fig. 1. Flow of trials through the stages of the meta-analysis.

correlation coefficients for continuous data. The reliability of the coding form was .88 across all variables. The interrater-reliabilities for the single items ranged between .55 and 1.00, with 83% of the items reaching reliability indices greater than .75. Coding discrepancies were discussed and resolved.

2.4. Effect size calculation

Effect sizes for the 39 controlled trials were computed using Hedges' *g*,

$$g = \bar{X}_{EG} - \bar{X}_{CG} / \sqrt{((n_{EG} - 1)SD_{EG}^2 + (n_{CG} - 1)SD_{CG}^2) / n_{EG} + n_{CG} - 2},$$

which refers to the mean difference between experimental (EG) and control group (CG) divided by the pooled standard deviation (Hedges and Olkin, 1985). In 14 studies BFB was compared to untreated control groups (i.e., headache monitoring, waiting list) and in 25 studies to active control treatments. In multiple active treatment comparisons Hedges' *g* provides information about the comparative effectiveness

or equivalence of different treatments. In order to evaluate the unique effect of BFB we additionally computed pre–post effect sizes in those cases.

Thus, pre–post effect sizes were computed for the 16 studies without control groups (i.e., pre–post trials) and the 25 studies with active control groups using the effect size statistic

$$g_{pre-post} = (\bar{X}_{post} - \bar{X}_{pre}) / \sqrt{SD_{pre}^2 + SD_{post}^2 - 2 \cdot r_{pre/post} \cdot SD_{pre} \cdot SD_{post}}$$

(McGaw and Glass, 1980; Gibbons et al., 1993).² This formula takes the pre–post correlations of the outcome variables into account and is therefore recommended for repeated measurement designs (Johnson, 1989; Hartmann and Herzog,

² Combining effect sizes from different study designs requires the transformation of all effect sizes into a common metric (Morris and DeShon, 2002). As this meta-analysis focuses on mean changes in headache activity, the appropriate effect size metric is the change score metric.

1995). We calculated the pre–post correlations of the outcome variables from raw data, if they were not reported in the studies and averaged them sample-size-weighted. The resulting pre–post and pre-follow-up correlations of all headache diary variables³ were based on a subsample of seven studies with 208 migraine patients. The pre–post correlations of the psychological outcome variables were obtained from test handbooks (e.g., BDI, STAI) or estimated with $r = .50$ for test–retest intervals shorter than six months and $r = .30$ for greater intervals (Smith et al., 1980), if no test–retest measures were available.

Effect sizes were calculated separately for each outcome variable, treatment group and time point, resulting in a total of 458 interdependent effect sizes, with a median of eight effect sizes per study. The correction for small sample bias was applied to effect sizes resulting in the unbiased estimator d (Hedges and Olkin, 1985).

2.5. Missing data

In studies that did not report means and standard deviations for the effect size calculation ($n = 15$), we computed algebraically equivalent effect sizes from t , F , r and χ^2 statistics, exact probability levels and odds ratios (Rosenthal, 1994; Ray and Shadish, 1996). In studies reporting only upper significance bounds ($n = 4$), we inferred effect size estimates by transforming $p < .05$ into $p = .05$ and $p < .01$ into $p = .01$. Written descriptions of “nonsignificant” results were transformed into $d = 0$. In case of incompletely reported statistical analysis (i.e., when measured outcome variables were missing in Section 3) we imputed zero effects. This conservative method leads to lower limit effect sizes, thus taking into account the inaccuracies in reporting (Rosenthal, 1994).

Dropout rates from the different treatment phases were coded as part of the internal validity of each study, according to predefined cut-off points of excellence and of minimal requirement (Rief and Hofmann, in press).

2.6. Integration of effect sizes

2.6.1. Integration of dependent effect sizes

Most studies used multiple outcome measures, thereby producing dependent effect sizes as a function of intercorrelations between assessment scales. The number of outcome variables ranged from 1 to 10 with a median of 3.5 per study. The most commonly used variables were frequency, duration and intensity of migraine as well as headache and medication composite scores. We pooled the outcome on all available headache variables to outline the general efficacy of BFB for migraine and additionally presented average effect sizes for all specific headache variables, including frequency of migraine attacks (i.e., the recommended primary outcome measure for clinical headache trials, IHS, 2000).

Psychological outcome variables were anxiety, depression and self-efficacy. Dependent effect sizes were also caused by the multiple use of a single control group to establish effect sizes of different active treatment groups, as it is common in multiple treatment studies ($n = 12$). These dependencies were handled by averaging the multiple outcome effect sizes within treatment groups and the multiple treatment effect sizes within studies. To obtain the variances of the mean effects, the individual effect size variances were averaged with covariance adjustment (Gleser and Olkin, 1994).⁴

2.6.2. Integration of independent effect sizes

We weighted the effect sizes d by the inverse of their sampling variances (Hedges and Olkin, 1985) and calculated mean d 's by averaging the weighted effects. To adequately address all of our research questions, separate integrations were carried out with respect to different types of outcome measures, interventions and time points. The homogeneity statistic Q (Shadish and Haddock, 1994) was calculated to determine whether each set of d 's shared a common population effect size. A fixed effects model (FEM) was used to compute average effect sizes when homogeneity was given; a random effects model (REM) was applied when the assumption of homogeneous effects was rejected. Integrations in the REM result in more conservative confidence intervals of the average effects on the one hand and further generalizability of inferences on the other hand (Hedges and Vevea, 1998).

2.7. Moderator analysis

Moderating effects of treatment types were tested by dividing the studies into classes based on treatment characteristics (i.e., feedback modalities) and testing for homogeneity of effect sizes between and within classes (a procedure analogous to the F test in an analysis of variance). The statistic Q_b was used as an omnibus test for significant differences between the groups. Q_w was used to test for homogeneity within classes as a global goodness-of-fit test. The presence of moderators is indicated by heterogeneity between classes (significant Q_b) and homogeneity within classes (nonsignificant Q_w).

A weighted least squares multiple regression of the individual effect sizes weighted by the inverse of their variances was conducted to identify additional moderators (Steel and Kammerer-Mueller, 2002). Correction formulas (Hedges, 1994) were applied to compute the standard errors and significance levels of the regression coefficients and the multiple correlation coefficients (R^2). The weighted sum of squares of the regression model (Q_r) was used as an omnibus significance test for the set of predictors. The model fit was tested with the error sum of squares (Q_e), indicating whether systematic unexplained variance remained in the regression model. Methodological variables as well as patient and treatment characteristics were used as predictors.

³ The resulting pre–post correlations were .69 for headache frequency, .63 for headache intensity, .78 for duration of migraine attacks, .62 for the headache index and .64 for the medication-index.

⁴ Intercorrelations of headache variables were calculated at post treatment and ranged from .35 for intensity and headache index to .93 for frequency and headache index.

2.8. Sensitivity analyses

2.8.1. Publication bias

Results of a meta-analysis may be biased due to the fact that studies with nonsignificant results are less likely to be published than those leading to significant results (an effect also known as the file drawer problem). This potential publication bias was examined graphically with a funnel plot analysis and numerically with the fail-safe N criterion (Rosenthal, 1979).

2.8.2. Intention-to-treat analysis

Missing data from dropouts represent a well-known potential bias to treatment studies. Intention-to-treat analysis is a widely recommended solution to it in primary research (Wright and Sim, 2003), as well as in meta-analysis (Moher et al., 1999). We imputed missing data from patients who dropped out of a study after randomization with zero effects (Higgins and Green, 2005), assuming that dropouts were nonresponders to BFB. The individual d 's were corrected with the zero effects and reintegrated with respect to the altered sample sizes.

2.8.3. Varying formulas for effect size calculation

Differences between Hedges' d and its pre-post equivalent have been described to influence meta-analytical results (Hartmann and Herzog, 1995). To analyse the impact of the method of effect size calculation, we separately integrated and compared effect sizes and variances that were based on varying formulas (Ray and Shadish, 1996).

3. Results

3.1. Descriptive statistics of the study sample

In this meta-analysis we reviewed the results of 55 clinical outcome studies. A basic description of all integrated studies is presented in Table 1.

3.1.1. Treatment characteristics

Our analyses included 117 treatment conditions, of which 84 were active BFB and 33 control conditions. A total of 35 conditions consisted of TEMP-FB in combination with either relaxation training or EMG-FB, 19 groups examined BVP-FB and seven treatment groups consisted of EMG-FB. Electroencephalogram feedback (EEG-FB, three groups), skin conductance feedback (four groups) and forehead temperature feedback (two groups) were examined less frequently. The number of BFB sessions ranged from 3 to 24 ($M = 11.0$ sessions, $SD = 4.3$). The control conditions included 14 untreated control groups, 12 placebo control conditions and seven alternative treatments, of which five were relaxation therapies and two were pharmacotherapies. Placebo control conditions consisted of 8 pseudofeedback⁵ groups, three relaxation-without-instruction groups and one pseudo-

meditation group. In 15 studies the stability of BFB treatment effects was examined. Four of them reported only follow-up data and 11 reported post treatment outcome as well. The analysis of follow-up effects included 24 active BFB conditions. The follow-up periods ranged from 6 to 60 months ($M = 14.7$, $SD = 14.7$).

3.1.2. Patient characteristics and attrition

The total number of patients across all studies, treatment and control groups combined, was 2229 migraine patients, with an average of 15.7 patients per study. One thousand seven hundred eighteen patients were assigned to BFB groups and 511 to control groups. In 45 studies age and sex of the examined patient sample was reported. The average age of patients was 37.1 ($SD = 10.0$)⁶ and 88.6% of the patients were female. In 31 studies the history of headache problems was reported. The average number of years patients suffered from migraine was 16.9 ($SD = 10.8$).

A total of 315 dropouts after treatment assignment were reported across all groups, representing a completion rate of 85.9% at post-treatment. Completion rates were similar for BFB (86.2%) and control groups (84.9%). The completion rate for the follow-up conditions was 95.0%. None of the integrated studies reported intention-to-treat analyses.

3.1.3. Outcome measures and validity

We integrated all outcome variables into two symptom categories, indexing headache pain and associated psychological symptoms. Headache pain included frequency, duration, and intensity of migraine attacks, consistently measured with a structured headache diary. Only four studies used other measures than a structured diary to assess headache. The headache diaries consisted of 1–7 headache variables, with a mean of three outcome measures ($SD = 2.4$) and were employed for an average of 4 weeks at baseline ($SD = 1.12$), post-treatment ($SD = 1.4$) and follow-up ($SD = 2.3$), respectively.

According to our 12 point validity scale, the validity of all integrated studies ranged from 3 to 11, averaging 7.3 ($SD = 2.0$), with similar validity scores resulting for the pre-post studies ($n = 51$, $M = 7.4$, $SD = 2.0$) and the follow-up studies ($n = 15$, $M = 6.8$, $SD = 1.4$).

3.2. General efficacy of BFB

Effect size calculation yielded 84 independent effect measures for headache relief from pre- to post-treatment. The effect sizes ranged from $d = -0.07$ to $d = 1.74$, forming a unimodal and symmetrical distribution. Table 2 shows the weighted average effect sizes,

⁵ Patients in pseudofeedback conditions were equally trained to influence physiological parameters, but in opposite direction (e.g., finger cooling) or under false feedback.

⁶ Grand means and SDs of the patient characteristics were established by sample-size-weighted averaging of the means and SDs reported in the primary studies.

Table 1
Design, treatment features and effect sizes for all included studies

Study	N	Treatment	Design	Follow-up ^d	Dropouts ^c	Headache variables			Psychological variables		
						<i>d</i> ^f	95%	CI	<i>d</i> ^f	95%	CI
Allen and Mills (1982)	8	BVP-FB	Pre-post		11	1.14*	0.27	2.00	–	–	–
Andrasik et al. (1984)	16	TF + PMR irregular contact	RCT	12	13 ^{bc}	0.64	0.10	1.19	–	–	–
	15	TF + PMR booster treatment		12	–	0.66	0.10	1.22	–	–	–
Andreychuk and Skriver (1975)	9	TF + AT	RCT	–	2	0.91*	0.11	1.70	–	–	–
	9	EEG + AT		–	2	0.77*	0.03	1.52	–	–	–
	10	Hypnosis		–	1	0.83*	0.11	1.54	–	–	–
Bild and Adams (1980)	7	VCT	RCT	–	3 ^b	1.74*	0.46	3.02	–	–	–
	6	EMG-FB (frontalis)		–	–	0.82	–0.36	1.99	–	–	–
	6	Headache monitoring/waiting list		–	–	–	–	–	–	–	–
Blanchard et al. (1982a)	8	PMR ^a + TF (migraine)	Pre-post	–	1	0.60	–0.16	1.36	–	–	–
	8	PMR ^a + TF (mixed headache)		–	0	0.84*	0.02	1.66	–	–	–
Blanchard et al. (1982b)	14	PMR ^a + TF (migraine)	Pre-post	–	6	0.59*	0.04	1.14	–	–	–
	14	PMR ^a + TF (mixed headache)		–	7	0.79*	0.22	1.36	–	–	–
Blanchard et al. (1988)	9	TF + RT clinic-based	RCT	–	28 ^b	0.19	–0.47	0.85	–	–	–
	9	TF + RT clinic-based, min. contact		–	–	0.70	–0.04	1.44	–	–	–
	11	TF + RT home-based		–	–	1.05*	0.30	1.80	–	–	–
	10	TF + RT home-based, min. contact		–	–	0.76*	0.04	1.47	–	–	–
	9	TF + RT clinic-based		12	0 ^c	0.55	–0.16	1.25	–	–	–
	9	TF + RT clinic-based, min. contact		12	0 ^c	0.68	–0.05	1.41	–	–	–
	11	TF + RT home-based		12	0 ^c	0.79*	0.10	1.47	–	–	–
Blanchard et al. (1990a)	10	TF + RT home-based, min. contact		12	0 ^c	1.00*	0.23	1.77	–	–	–
	30	TF + RT	RCT	–	8	0.29	–0.09	0.68	–	–	–
	29	TF + RT + coping		–	9	0.39	0.00	0.77	–	–	–
Blanchard et al. (1990b)	17	Headache monitoring/waiting list		–	4	0.03	–0.47	0.53	–	–	–
	32	TF + RT	RCT	–	8	0.50*	0.12	0.87	–	–	–
	30	TF + RT + CT		–	12	0.68*	0.28	1.08	–	–	–
Blanchard et al. (1978)	24	Pseudomeditation		–	6	0.37	–0.06	0.80	–	–	–
	30	Headache monitoring/waiting list		–	6	0.00	–0.37	0.38	–	–	–
	10	TF + RT + home practice	RCT	–	2	0.52	–0.06	1.09	–	–	–
	10	RT + home practice		–	2	0.78*	0.20	1.37	–	–	–
Blanchard and Kim (2005)	10	Headache monitoring/waiting list		–	3	–	–	–	–	–	–
	9	TF + RT (menstrual migraine)	Pre-post	–	0	0.92*	0.13	1.72	–	–	–
Blanchard et al. (1994)	3	TF + RT (non-menstrual migraine)		–	0	0.96	–0.51	2.43	–	–	–
	15	TF + RT (high-success feedback)	RCT	–	2	0.46	–0.10	1.02	2.28*	0.90	3.67
Blanchard et al. (1991)	13	TF + RT (modest success feedback)		–	0	0.08	–0.49	0.64	0.81	–0.06	1.68
	23	TF + RT + home practice	RCT	–	5	0.36	–0.08	0.80	–	–	–
Blanchard et al. (1997)	23	TF + RT		–	4	0.24	–0.19	0.68	–	–	–
	13	Headache monitoring/waiting list		–	3	–0.17	–0.75	0.40	–	–	–
	19	TF warming + RT	RCT	–	0	0.22	–0.26	0.70	–	–	–
	17	TF cooling + RT		–	0	0.42	–0.09	0.94	–	–	–
	16	TF stable		–	4	0.18	–0.34	0.70	–	–	–
Claghorn et al. (1981)	18	Alpha		–	1	0.39	–0.10	0.88	–	–	–
	6	TF warming	RCT	–	0	1.53*	0.41	2.65	–	–	–
Cohen et al. (1980)	5	TF cooling		–	0	0.38	–0.60	1.36	–	–	–
	34	TF/EMG-FB/EEG/VCT	RCT	8	8	0.09	–0.26	0.45	–	–	–

Daly et al. (1983)	10	TF + AT	RCT	–	0	0.91*	0.20	1.63	–	–	–
	10	EMG-FB + AT		–	0	0.82*	0.11	1.52	–	–	–
	11	PMR		–	0	0.29	–0.35	0.92	–	–	–
French et al. (1997)	14	TF high-success	RCT	–	3 ^b	0.97*	0.35	1.58	1.09*	0.38	1.79
	13	TF moderate-success		–	–	0.78*	0.16	1.40	0.56	–0.05	1.17
Friar and Beatty (1976)	10	VCT	RCT	–	0	0.51	–0.18	1.21	–	–	–
	9	VCT in the hand		–	0	0.11	–0.57	0.78	–	–	–
Gauthier et al. (1981)	6	TF warming	RCT		0	0.50	–0.39	1.38	–	–	–
	6	TF cooling			0	0.54	–0.36	1.43	–	–	–
	6	Artery warming			0	0.30	–0.57	1.17	–	–	–
	6	Artery cooling			0	0.76	–0.16	1.68	–	–	–
	6	TF warming		6	0 ^c	0.40	–0.48	1.29	–	–	–
	6	TF cooling		6	0 ^c	0.67	–0.25	1.59	–	–	–
	6	Artery warming		6	0 ^c	0.12	–0.45	1.00	–	–	–
	6	Artery cooling		6	0 ^c	0.33	–0.55	1.21	–	–	–
Gauthier et al. (1994)	8	TF + home training	RCT	–	0	0.94*	0.11	1.76	–	–	–
	9	TF		–	0	–0.07	–0.75	0.62	–	–	–
Gauthier et al. (1983)	7	Vasoconstriction	RCT	–	0	0.56	–0.27	1.39	–	–	–
	7	Vasodilation		–	0	1.03*	0.16	1.90	–	–	–
	7	Headache monitoring/waiting list		–	0	–0.11	–0.92	0.69	–	–	–
Gauthier et al. (1988)	22	VCT/TF (common migraine)	Pre-post-fu		0	0.95*	0.46	1.44	–	–	–
	17	VCT/TF (classic migraine)			0	1.07*	0.51	1.63	–	–	–
	22	VCT/TF (common migraine)		6	0 ^c	1.02*	0.53	1.51	–	–	–
	17	VCT/TF (classic migraine)		6	0 ^c	1.07*	0.50	1.63	–	–	–
Gauthier et al. (1985)	7	VCT	RCT	–	0	0.74	–0.36	1.85	–	–	–
	8	TF		–	0	1.25*	0.14	2.37	–	–	–
	7	Headache monitoring/waiting list		–	0	–0.01	–0.82	0.80	–	–	–
Gauthier and Carrier (1991)	96	VCT/TF	Pre-post-fu		0	0.60*	0.38	0.82	–	–	–
	96	VCT/TF		54	0 ^c	0.25*	0.03	0.47	–	–	–
Gauthier et al. (1991)	39	VCT/TF (menstrual migraineurs)	Pre-post-fu		0	0.74*	0.33	1.14	–	–	–
	39	VCT/TF (menstrual migraineurs)		6	0 ^c	0.72*	0.31	1.13	–	–	–
Grazzi and Bussone (1993a)	26	EMG-FB	Pre-post-fu		0	0.55*	0.14	0.97	0.16	–0.23	0.54
	26	EMG-FB		6	0	1.42*	0.87	1.97	0.47*	0.07	0.87
Grazzi and Bussone (1993b)	10	EMG-FB + RT	Pre-post-fu		0	1.02*	0.24	1.80	0.86*	0.16	1.57
	10	EMG-FB + RT		12	0	1.50*	0.57	2.43	0.40	–0.51	1.31
Holroyd et al. (1995)	14	TF + RT	RCT	–	2	0.72*	0.13	1.23	0.66*	0.11	1.22
	13	Propranol + TF + RT		–	4	1.09*	0.42	1.75	1.10*	0.46	1.74
Holroyd et al. (1988)	19	TF + RT	RCT	–	0	0.72*	0.21	1.22	0.31	–0.15	0.76
	18	Ergotamin + compliance training		–	0	0.46	–0.05	0.97	0.18	–0.28	0.64
Holroyd et al. (1989)	8	TF + RT	RCT		5 ^b	1.43*	0.41	2.45	–	–	–
	8	Ergotamin + compliance training			–	0.96*	0.11	1.82	–	–	–
	8	TF + RT		36	0 ^c	1.19*	0.26	2.12	–	–	–
	8	Ergotamin + compliance training		36	0 ^c	0.55	–0.20	1.30	–	–	–
Ilacqua (1994)	9	TF	RCT	–	1	1.02*	0.06	1.98	–0.25	–1.16	0.65
	9	Guided Imagery		–	1	1.91*	0.82	3.00	0.51	–0.41	1.42
	10	TF + Guided Imagery		–	0	0.42	–0.46	1.31	–0.96*	–1.88	–0.03
	10	Headache monitoring/waiting list		–	0	–	–	–	–	–	–

(continued on next page)

Table 1 (continued)

Study	N	Treatment	Design	Follow-up ^d	Dropouts ^e	Headache variables			Psychological variables		
						<i>d</i> ^f	95%	CI	<i>d</i> ^f	95%	CI
Johansson and Öst (1987)	14	TF + RT + home training (learner)	Pre-post-fu		4 ^b	0.83*	0.12	1.53	–	–	–
	10	TF + RT + home training (nonlearner)		–	–	0.00	–0.81	0.81	–	–	–
	14	TF + RT + home training (learner)		6	0 ^c	0.90*	0.19	1.61	–	–	–
	10	TF + RT + home training (nonlearner)		6	0.00	–0.81	0.81	–	–	–	
Jurish et al. (1983)	21	TF clinic-based	RCT	–	10 ^b	0.68*	0.20	1.16	–	–	–
	19	TF minimal contact home-based		–	–	0.90*	0.38	1.41	–	–	–
Kewman and Roberts (1980)	11	TF warming	RCT	–	7 ^b	0.70*	0.02	1.37	0.50	–0.11	1.12
	12	TF cooling		–	–	0.62	–0.01	1.25	0.15	–0.71	1.00
Kim and Blanchard (1992)	11	Headache monitoring/waiting list	Pre-post	–	–	0.45	–0.20	1.10	0.60	–0.03	1.22
	60	TF + PMR + CT (migraine)		–	0	0.66*	0.37	0.94	–	–	–
	38	TF + PMR + CT (menstrual migraine)		–	0	0.46*	0.12	0.80	–	–	–
Knapp and Florin (1981)	15	TF (menstrual migraine)	Pre-post	–	0	0.19	–0.44	0.83	–	–	–
	12	VCT + stress coping/VCT		RCT	–	0	0.55	–0.06	1.16	–	–
Kroener (1982)	4	Headache monitoring/waiting list	RCT	–	0	0.00	–0.98	0.98	–	–	–
	16	EMG-FB (frontalis)		–	9 ^b	0.28	–0.24	0.80	–	–	–
	16	EMG-FB (frontalis) + home training		–	–	0.17	–0.35	0.68	–	–	–
	15	EMG-FB (trapezius)		–	–	0.54	–0.01	1.09	–	–	–
	17	SCF		–	–	0.19	–0.31	0.69	–	–	–
	15	SCF + home training		–	–	0.38	–0.16	0.92	–	–	–
	13	Pseudofeedback		–	–	0.16	–0.41	0.73	–	–	–
Kropp et al. (1997)	12	Headache monitoring/waiting list	RCT	–	–	0.19	–0.40	0.79	–	–	–
	19	BVP-FB		–	0	0.53	–0.13	0.99	–	–	–
Lake et al. (1979)	19	CBT	RCT	–	0	0.37	–0.21	0.90	–	–	–
	6	TF + RET		–	0	0.62	–0.54	1.78	–	–	–
	6	TF		–	0	0.83	–0.35	2.01	–	–	–
	6	EMG-FB		–	0	1.46*	0.19	2.73	–	–	–
Largen et al. (1981)	6	Headache monitoring/waiting list	RCT	–	0	–	–	–	–	–	–
	6	TF (warming) + PMR		–	2 ^b	1.25*	0.15	2.34	–	–	–
Lisspers and Öst (1990)	5	TF (cooling) + PMR	Pre-post-fu	–	–	0.54	–0.40	1.47	–	–	–
	50	TF/BVP-FB		–	13	0.31	–0.25	0.87	–	–	–
Marcus et al. (1998)	50	TF/BVP-FB	Pre-post	12	0 ^c	1.33*	0.72	1.94	–	–	–
	69	TF + PMR + PT		–	15	0.64*	0.41	0.87	–	–	–
McGrady et al. (1994)	11	TF + EMG-FB + AT	RCT	–	0	0.27	–0.33	0.87	0.23	–0.37	0.82
	12	Self-relax		–	0	–0.03	–0.60	0.54	0.37	–0.21	0.95
Medina et al. (1976)	13	TF + EMG-FB + AT (migraine)	Pre-fu	12	0	1.15*	0.48	1.81	–	–	–
	14	TF + EMG-FB + AT (mixed headache)		12	0	0.26	–0.30	0.81	–	–	–
Mizener et al. (1988)	11	TF + AT	Pre-post	–	14	–	–	–	0.62	0.00	1.24
Mullinix et al. (1978)	6	TF	RCT	–	0	0.57	–0.30	1.45	–	–	–
	5	TF (false feedback)		–	1	0.09	–0.79	0.97	–	–	–
Neff et al. (1983)	13	PMR ^a + TF (low absorption)	Pre-post	–	0	0.39	–0.01	0.79	–	–	–
	8	PMR ^a + TF (high absorption)		–	0	0.54*	0.02	1.06	–	–	–
Nicholson and Blanchard (1993)	7	TF + EMG-FB + PMR	RCT	–	0	1.50*	0.22	2.78	0.40	–0.13	0.94
	7	Headache monitoring/waiting list		–	0	0.45	–0.31	1.21	–	–	–
Sargent et al. (1986)	102	EMG-FB + AT/TF + AT	RCT	–	57 ^b	0.48*	0.18	0.78	–	–	–
	34	Headache monitoring/waiting list		–	–	–	–	–	–	–	–
Silver et al. (1979)	18	TF + AT	RCT	12	4 ^{b,c}	0.58*	0.03	1.21	–	–	–

Sorbi and Tellegen (1984)	18	PMR	12	–	0.58*	0.03	1.12	–	–	–
	10	TF + SC + AT	RCT	3 ^b	0.54	–0.12	1.21	–	–	–
	9	SC + AT		–	0.80*	0.07	1.54	–	–	–
	10	TF + SC + AT		7	0 ^c	–0.03	1.38	–	–	–
	9	SC + AT		7	0 ^c	–0.28	1.13	–	–	–
Turin and Johnson (1976)	6	TF (warming)	RCT	1	1.18*	0.20	2.15	–	–	–
	3	TF (cooling)		0	–	–	–	–	–	–
Vasudeva et al. (2003)	20	EMG-FB + TF + AT	RCT	15 ^b	0.76*	0.26	1.26	0.92*	0.35	1.48
	20	Self-relax		–	0.10	–0.47	0.68	0.11	–0.40	0.62
Wauquier et al. (1995)	12	EMG-FB + TF + AT	RCT	0	0.82*	0.17	1.48	0.76*	0.16	1.36
	13	Self-relax		0	0.15	–0.43	0.73	0.08	–0.47	0.62

Note: TF, peripheral skin temperature feedback (TEMP-FB); BVP-FB, blood-volume-pulse feedback (vasoconstriction and dilation), VCT, vasoconstriction training (temporalis artery); EMG-FB, electromyography feedback; EEG, electroencephalography feedback/neurofeedback; alpha, EEG feedback for alpha frequency bands; RT, relaxation training; AT, autogenic relaxation training; PMR, progressive muscle relaxation; CT, cognitive therapy; SC, stress coping; RET, rational emotive therapy; PT, physiotherapy.

^a PMR nonresponder.

^b Number of dropouts over all treatment conditions in a study.

^c Number of dropouts at follow-up.

^d Length of follow-up measurement in months.

^e Number of dropouts after assignment to treatment conditions.

^f *d* indicates the standardized mean difference according to Hedges' *g* (Hedges and Olkin, 1985) and its pre-post equivalent (McGaw and Glass, 1980).

* Individual effect size differs significantly from zero (i.e., confidence interval (CI) does not include zero).

95% CIs and homogeneity statistics for each treatment comparison. The effect sizes were homogeneous. BFB yielded a significant medium effect size; the narrow confidence interval confirms the robustness of this effect. In comparison to waiting list control groups BFB yielded a significant small-to-medium effect size. An average small-to-medium effect size was also found in comparison to placebo control groups (pseudo-feedback and pseudo-relaxation). However, this effect missed formal significance. No significant difference between BFB and either relaxation (mostly progressive muscle relaxation) or ergotamine treatment was found. Note, however, that both pharmacotherapy studies revealed small-to-medium effect sizes in favour of BFB.

In a sensitivity analysis we separately integrated and compared effect sizes based on varying formulas. The results were robust for the comparison of Hedges' *d* from RCTs with Hedges' $d_{pre-post}$ from pre-post trials (Hedges' *d*: $\bar{d} = 0.45$, 95% CI = 0.26, 0.63, $Q = 8.77$, $p(Q) = 0.79$; Hedges' $d_{pre-post}$: $\bar{d} = 0.57$, 95% CI = 0.51, 0.64, $Q = 74.89$, $p(Q) = 0.59$), as well as for the comparison of effects sizes computed from means and standard deviations with those computed from other test statistics (means and standard deviations: $\bar{d} = 0.56$, 95% CI = 0.49, 0.64, $Q = 44.57$, $p(Q) = 0.69$; other test statistics: $\bar{d} = 0.60$, 95% CI = 0.50, 0.70, $Q = 34.97$, $p(Q) = 0.37$).

3.3. Follow-up treatment effects

We calculated 24 independent follow-up effect sizes ($N = 469$). They ranged from $d = 0.09$ to $d = 1.50$, forming a unimodal and symmetrical distribution. The weighted integration in the FEM resulted in a significant Q statistic, revealing heterogeneity within the follow-up effect sizes. Aggregation in the REM resulted in a significant medium-to-large average effect size ($\bar{d} = 0.69$, 95% CI = 0.51, 0.88, $Q = 20.09$). A significant proportion ($\tau^2 = 0.10$) of unexplained variance was revealed, indicating the need to investigate the impact of moderator variables.

3.4. Efficacy for different types of outcome variables and feedback modalities

As shown in Table 3, the average effect sizes for all different headache outcome variables were significant and of medium-to-large magnitude. The psychological variables self-efficacy and depression yielded significant medium-to-large effect sizes as well, while anxiety obtained a significant small-to-medium effect. The reductions in headache frequency and duration were significantly stronger than the reduction of medication-intake (i.e., medication-index), indicated by the non-overlapping CIs. Self-efficacy yielded the highest effect size among the psychological variables, showing signifi-

Table 2
Mean weighted effect sizes as a function of treatment comparison

Comparison	<i>k</i>	<i>N</i>	Fixed effects model		
			\bar{d}	95% CI	<i>Q</i>
Pre- vs. post-treatment	84	1480	0.58	0.52, 0.64	78.97
BFB vs. no-treatment control	14	574	0.45	0.26, 0.63	8.77
BFB vs. placebo control	12	340	0.25	0.00, 0.49	4.05
BFB vs. relaxation	5	136	0.10	−0.39, 0.59	3.59
BFB vs. pharmacotherapy	2	52	0.30	−0.33, 0.94	0.08

Note: *k*, number of effect sizes; *N*, number of migraine patients; \bar{d} , weighted mean effect size; 95% CI, confidence interval for \bar{d} ; *Q*, homogeneity statistic for \bar{d} calculated via fixed effect model.

cantly stronger improvement than the medication-index. The CIs of all other headache and psychological parameters did not show any significant differences.

Holroyd and Penzien (1990) showed that improvements in headache activity were about 20% greater when assessed with other instruments than structured diaries. The present meta-analysis also revealed a numerically higher effect size for the four studies using other headache measures (headache diary: $\bar{d} = 0.58$, 95% CI = 0.51, 0.64, $Q = 75.13$, $p(Q) = 0.63$; other headache measures: $\bar{d} = 0.86$, 95% CI = 0.45, 1.27, $Q = 2.07$, $p(Q) = 0.56$). However, probably due to the small number of studies using non-headache diary measures (i.e., three studies using questionnaires, one study using a potentiometer) this difference was statistically not reliable.

As shown in Table 4, the average effect sizes for all feedback modalities were significant and of medium-to-large magnitude. Significant differences between modalities were not observed, as indicated by the between group homogeneity statistic ($Q_b = 5.34$, $p = .25$; overall model fit: $Q_w = 73.63$, $p = .65$). Thus, all BFB modalities proved to be equally effective in the reduction of migraine symptoms. Notably, BVP-FB, that is the modality not evaluated in prior meta-analyses, yielded the highest symptom reductions, indicating that this method is at least as effective as the more widely used ones.

3.5. Influence of patient and treatment characteristics and validity

Five predictors were tested in two weighted regression models of the pre–post and the follow-up effect sizes, respectively.

The moderators a priori hypothesized were: treatment setting (1 = with home training, 0 = without home training), years with migraine (years since first diagnosis), gender and age of migraine patients and the validity sum score as a methodological predictor. The results for the prediction of direct treatment effects are presented in Table 5. The patient and treatment characteristics yielded significant regression coefficients, while the influence of the methodological quality of the studies was insignificant. Treatment setting was the best predictor, indicating that BFB in combination with home training yielded nearly 20% higher effect sizes than mere outpatient therapies. All five moderators explained a significant amount of variance in the effect sizes ($Q_r = 11.72$, $p < .05$; $R^2 = .26$). The insignificant Q_e statistic indicates that the model was correctly specified ($Q_e = 70.59$, $p = .71$).

In a second multiple regression analysis these five predictors were used to explain the variance in the follow-up effect sizes (see Table 5). The patient characteristics age and sex had no significant influence on the follow-up effect sizes. The influence of the years with migraine, as measured with the mean number of headache years, was negatively associated with the follow-up effect sizes and yielded the highest standardized regression coefficient. The influence of the treatment setting was significant as well. Thus, the importance of home training for the efficacy of BFB, as shown above for the pre–post effect sizes, was replicated with the follow-up effect sizes. The validity rating yielded a significant negative regression coefficient, indicating that the studies of higher methodological quality report smaller follow-up effect

Table 3
Mean weighted pre–post effect sizes as a function of symptom category

Symptom category	<i>k</i>	<i>N</i>	\bar{d}	95% CI	<i>Q</i>
Frequency	33	623	0.70	0.60, 0.80	32.05
Duration ^a	30	422	0.67	0.52, 0.82	30.45
Intensity ^a	39	689	0.61	0.49, 0.76	37.14
Headache-index	46	814	0.58	0.50, 0.65	41.43
Medication-index	51	982	0.44	0.37, 0.51	54.05
Self-efficacy	7	68	0.89	0.58, 1.19	6.45
Depression	6	90	0.57	0.34, 0.80	9.14
Anxiety	7	112	0.44	0.24, 0.64	10.38

Note: *k*, number of effect sizes; *N*, number of migraine patients; \bar{d} , weighted mean effect size, 95% CI, confidence interval for \bar{d} ; *Q*, homogeneity statistic for \bar{d} ; ^aintegrations carried out in the random-effects model; τ^2 , random-effects variance ($\tau^2(\text{duration}) = 0.07$; $\tau^2(\text{intensity}) = 0.05$).

Table 4
Analysis of variance in effect sizes as a function of type of feedback modality

Feedback modality	<i>k</i>	<i>N</i>	Fixed effects model		
			\bar{d}	95% CI	Q_{wi} (p)
TEMP-FB + RT/EMG	35	777	0.60	0.51, 0.68	28.95 (.71)
TEMP-FB	19	221	0.52	0.37, 0.67	20.82 (.29)
BVP-FB	16	306	0.68	0.54, 0.82	16.43 (.35)
EMG-FB	7	105	0.50	0.29, 0.72	5.15 (.53)
Other	7	71	0.40	0.15, 0.65	2.28 (.89)

Note: TEMP-FB + RT/EMG, TEMP-FB in combination with relaxation or EMG-FB; other, EEG feedback, skin conductance feedback, forehead temperature feedback; *k*, number of independent effect sizes; *N*, number of migraine patients; \bar{d} , weighted mean effect size, 95% CI, confidence interval for \bar{d} ; Q_{wi} , homogeneity within each group.

sizes. The Q_r statistic confirmed the overall significance of the regression model. All five moderators explained a significant and substantial amount of the variance in the follow-up effects ($Q_r = 26.55, p < .01; R^2 = .80$). Q_e was not significant indicating that the model was correctly specified ($Q_e = 27.75, p = .07$).

3.6. Publication bias

A sample of primary studies is unbiased and representative for the relevant study-population, if the individual effect sizes are normally distributed and independent of sample size. Graphical tests of this prerequisite are presented in Fig. 2. The distribution of effect sizes assumes the typical shape of a funnel plot (Fig. 2a) and deviations from the normal distribution are minimal as demonstrated with the normal quantile plot in Fig. 2b (Wang and Bushmann, 1998).

In addition to this graphical method publication bias was examined using the fail-safe *N* criterion (Rosenthal, 1979). This criterion represents the number of unpublished studies with a zero effect that would – if available for meta-analysis – reduce the overall effect size to zero. Fail-safe *N* should be at least five times the number of studies included in the meta-analysis (Rosenthal, 1979). We calculated a fail-safe *N* of 4776 for the critical

effect size of $\bar{d} = 0.01$. Thus, 4776 unpublished studies with zero effects would be necessary to reduce the observed average effect of $\bar{d} = 0.58$ to zero. In sum, publication bias can be ruled out.

3.7. Intention-to-treat analysis

The intention-to-treat analysis resulted in a significant medium effect size ($N = 1718, k = 84, \bar{d} = 0.53; 95\% \text{ CI: } 0.45, 0.60$), based on an homogeneous distribution of single effect sizes ($Q = 60.76; p(Q) = 0.97$). Thus, the mean treatment effect of BFB remained stable and decreased only slightly, when drop-outs were considered as nonresponders.

4. Discussion

4.1. Resume

The results of the present meta-analysis provide strong evidence of the efficacy of BFB for migraine, through the integration of a total of 55 studies. The size of the treatment effect represents a symptom reduction of more than half a standard deviation, which was consistently found in the reviewed literature and is also remarkably high in the area of chronic pain. The treatment effects remained stable over an average follow-up interval of more than one year. These findings provide the first meta-analytical proof for the long-term outcome of BFB for migraine. Superior clinical results emerged for BFB compared to waiting list control. At least equal efficacy levels were obtained in comparison to psychological placebo controls,⁷ relaxation and pharmacotherapy. Frequency and duration of migraine attacks were reduced significantly more than the medication-intake, which provides further evidence of the prophylactic potential of BFB. Moreover, BFB does not

Table 5
Multiple regression models for the prediction of treatment effects

Predictors	<i>b</i>	β	<i>t</i> -Value
Direct treatment effects			
Validity rating	-.00	-.00	-0.20
Treatment setting	.17	.27	20.07**
Percentage of female patients	.00	.11	5.60**
Mean age of patients	-.02	-.20	13.75**
Mean number of headache years	.01	.11	7.20**
Follow-up effects			
Validity rating	-.09	-.23	-7.02**
Treatment setting	.28	.30	6.66**
Percentage of female patients	.00	.04	0.70
Mean age of patients	.01	.07	1.01
Mean number of headache years	-.13	-.77	-13.27**

Note: *k*, number of effect sizes; *N*, number of migraine patients; *b*, unstandardized regression coefficient; β , standardized regression coefficient; *SE*, standard error of *b*; *t*-value, *t*-value of *b*; ** $p < .01$.

⁷ The finding that BFB was not superior to placebo controls may be partly due to the diversity and the active treatment components (e.g., pseudofeedback, pseudomeditation) of the integrated psychological placebo control groups and should therefore be interpreted with caution.

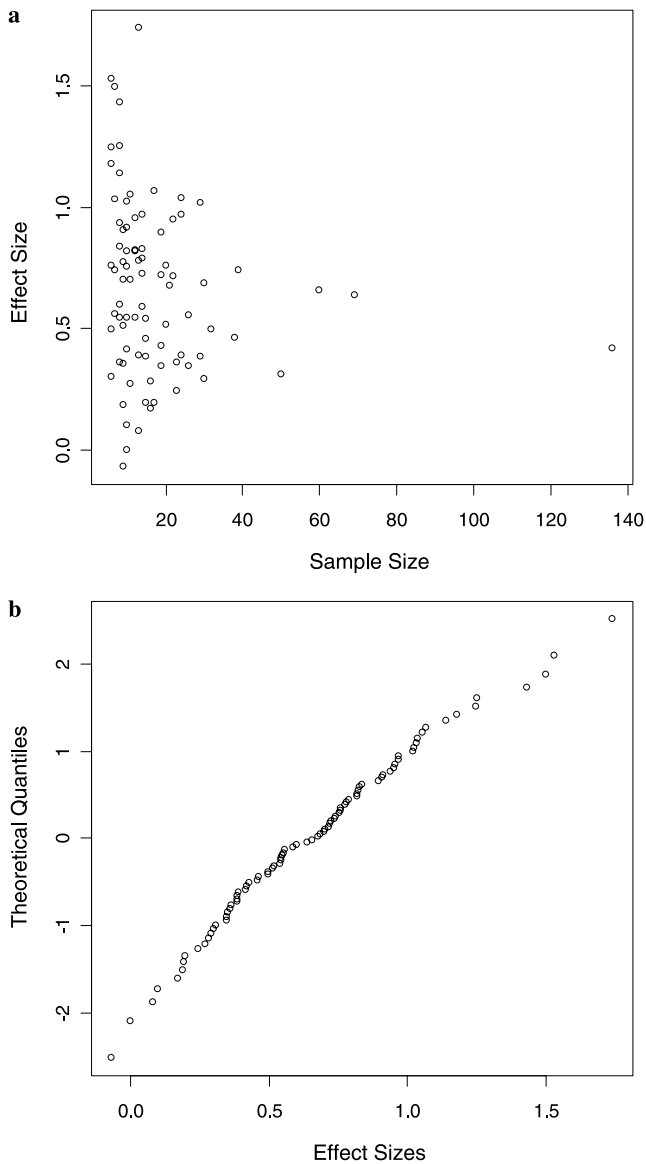


Fig. 2. Graphical analysis of publication bias. (a) Funnel plot. Effect sizes d (independent pre-post effect sizes estimating the symptom reduction on all headache variables through biofeedback therapy) displayed as a function of the sample size of each study ($k = 84$). (b) Normal quantile plot. Effect sizes d displayed against the expected quantiles of the normal distribution.

only reduce the main symptoms of migraine, it also reduces the associated symptoms of depression and anxiety and affects cognitive processes by enhancing patients' self-efficacy. BVP-FB, EMG-FB and TEMP-FB alone or in combination are equally efficacious in the treatment of migraine. However, BVP-FB yielded the numerically highest effect size of all examined feedback modalities. Additional home training enhanced the direct and the follow-up treatment effect sizes, whereas the influence of patient characteristics differed between direct and long-term effect sizes. Finally, potential contributions of methodological artefacts to the

observed effect sizes like selective dropout or publication bias could be ruled out.

4.2. Clinical and scientific implications

The established medium effect sizes for the efficacy of BFB that we found to be stable over follow-up periods up to several years are quite promising, considering that the average sample patient had been suffering from migraine for over 16 years. Also, the treatment was generally well accepted and none of the reviewed studies reported any adverse effects of BFB. The average attrition rates were rather low, both absolutely and relative to those reported in pharmacological studies (Holroyd and Penzien, 1990). This low dropout is partly due to an enhanced treatment adherence in behavioral trials, where none of the pharmacological side-effects are present. Thus, based on the present results BFB can be recommended to therapists, physicians and health care providers as an efficacious non-medical treatment alternative for highly chronified migraine patients; suitable also for the long-term prevention of migraine attacks.

In clinical practice, relaxation training still is the most widely used behavioral migraine treatment (Lipchik and Holroyd, 1999). In contrast, BFB is often only available in specialized clinics and headache centers. It may be speculated that this gap in utilization is not only due to the greater technical sophistication and cost involved in administering BFB, but also in a lack of knowledge of primary care physicians (Wenzel et al., 2005). Whatever the reasons for this unequal utilization may be, comparisons of the present results with meta-analytic evidence of the efficacy of relaxation (Goslin et al., 1999; Eccleston et al., 2002) lead us to the conclusion that the efficacy of BFB at least equals relaxation training. For a specific population of headache patients, who do not respond to relaxation, BFB has even been recommended as preferable treatment option (Blanchard et al., 1982a). As a consequence, BFB should be made more widely available.

In addition to these general recommendations the present results also provide some more specific insights. First, in several of the reviewed studies the follow-up effects were even higher than the immediate treatment effects, illustrating that symptom improvements were not only maintained through a notably long follow-up period, but also somewhat enhanced over time (Kroener, 1982; Blanchard, 1987; Gauthier and Carrier, 1991; Grazi and Bussone, 1993b). Several moderators have been suggested to underlie this sustained efficacy, for example, cognitive-attributional factors like improved self-efficacy (Blanchard, 1987) and the continued practice and application of self-regulation skills at home (Lisspers and Öst, 1990). Supporting the latter suggestion our multiple regression model revealed that additional therapy-accompanying home training is an important predictor of the long-term outcome. In addition, years with

migraine were found to be significantly associated with the treatment effects: More years with migraine predicted smaller follow-up effects, but – somewhat unexpectedly – higher effects during initial pre–post measurement. This result emphasizes the benefits of early treatment in the case of chronic headache and points towards the importance of special therapeutic attendance (e.g., booster care, encouragement to home training) for the maintenance of the pre–post treatment effects of BFB, particularly in patients with a long history of migraine.

Second, with regard to the different feedback modalities our results provide a trend for some migraine patients to benefit particularly from the application of BVP-FB. Our finding that BVP-FB yielded the numerically highest effect size is consistent with some earlier findings of Blanchard et al. (1980). However, future studies are needed to document the statistical reliability of the superiority of this promising technique.

Third, we found that self-efficacy yielded higher effect sizes than the actual pain related outcome measures of BFB. This observation nicely dovetails with self-regulatory models of chronic pain which postulate that treatment success is cognitively mediated. Thus, in future studies it will be of interest to directly investigate, whether changes in self-efficacy (and subsequent changes in coping strategies, Holroyd et al., 1984) or illness perceptions (and subsequent improvements in treatment adherence, Hobro et al., 2004) mediate the treatment effects of BFB.

Finally, in agreement with earlier observations (Kroner-Herwig and Sachse, 1988) we found that time related aspects (i.e., frequency and duration) of migraine tended to yield larger effect sizes than quality related pain experiences (i.e., intensity and medication-index). Similar findings have recently led to criticism of the widely adopted use of combined pain indices (Andrasik and Walch, 2001), highlighting the importance of specific pain-measures (Andrasik et al., 2005). In addition, our observation of particularly large effect sizes for the reduction of migraine-frequency further supports the efficacy of BFB, because frequency of migraine attacks should be used as primary efficacy measure for clinical headache trials (IHS, 2000).

4.3. Limitations

Since the publication of the first relevant headache trial 30 years ago the standards for analysing and publishing clinical trials were significantly improved (Begg et al., 1996; Moher et al., 2001). Furthermore, several recent studies discussed methodological features like the use of control groups (Rains et al., 2005), sample size and statistical power (Houle et al., 2005) as well as treatment integrity and blinding (Nash et al., 2005) as possible moderators of treatment effects in headache trials. Despite the well-known impact of study methodology

we used relatively liberal criteria for study-inclusion in order to be able to investigate potential moderating factors, resulting in variable methodological standards of the analysed studies and the need to integrate effect sizes from varying formulas (i.e., from control group and pre–post comparisons). We addressed most of these issues with our validity rating and found that study validity was not related to immediate treatment effects. We also ruled out the potential bias of varying effect size formulas in several sensitivity analyses. Thus, it seems reasonable to conclude that the presented results are unbiased and reliable for the pre–post effect sizes. However, for the follow-up effect sizes we observed a significant influence of study validity: On average, follow-up effect sizes \bar{d} decreased by 0.09 with every one-point increase in validity. Therefore, the reported average effect size for the long-term outcome might slightly overestimate the real effect. In sum, even though the estimates of follow-up effect sizes are somewhat unreliable, our method of study-inclusion provided both more powerful moderator tests and more generalizable results than would have been possible using more conservative inclusion criteria. Future research in the area of behavioral headache treatments would benefit from the application of current methodological standards (Penzien et al., 2005). Furthermore, we strongly recommend the use of multiple measures to assess treatment success, including aspects of pain as well as measures of quality of life, coping strategies, health service use and changes in functional level (i.e., work and occupational status).

Finally, it should be noted that some recent developments in the nondrug-treatment of migraine were not included in this meta-analysis, because no study investigating them met the inclusion criteria. Examples of such developments are alternative formats of administering BFB like home-based and minimal therapist-contact treatments (Rowan and Andrasik, 1996; Haddock et al., 1997) or Internet-based treatments (Devineni and Blanchard, 2005) as well as the application of Neurofeedback. Very promising results have recently been reported for the feedback of slow cortical potentials in children with migraine (Siniatchkin et al., 2000; Kropp et al., 2002); its efficacy for adult migraineurs is yet to be evaluated.

4.4. Conclusions

This meta-analysis documents medium effect sizes for the short- and long-term outcome of BFB for migraine in adults. BFB significantly and substantially reduces the pain and psychological symptoms of highly chronified patients within the scope of only 11 sessions. Thus, BFB can be recommended as an evidence-based behavioral treatment option for the prevention of migraine.

Acknowledgements

The authors would like to thank Frederike Schirmbeck for her help in coding the studies and Winfried Rief for his support and helpful comments on this work.

Appendix A.

Items of the structured coding scheme:

Identification: (1) identification number, (2) coder, (3) author, (4) publishing journal, (5) year of publication.

Methodology: (6) design (pre–post design vs. controlled design), (7) number of BFB and control groups, (8) measurement points (pre–post, pre–post–follow-up, only follow-up), (9) treatment allocation (randomized, pseudo randomized, not reported), (10) blinding (double blind, patient blinding, not specified), (11) type of outcome variables (headache intensity, duration, frequency, headache index, medication-index, anxiety, depression, self-efficacy etc.), (12) use of a structured headache diary (yes, no), (13) number of weeks of diary assessment at pre, post and follow-up measurement, (14) number of participants (overall, per group), (15) number of dropouts (after assignment, at follow-up), (16) research hypothesis (focused, diffuse, e.g., tested with more than one degree of freedom in the numerator of an F test and without specific contrasts), (17) statistical data for the calculation of effect sizes (means, standard deviations, other statistics).

Subjects: (18) diagnosis (classic or common migraine, vascular headache, menstrual migraine, tension type headache, migraine not otherwise classified), (19) diagnostic instruments (standardized diagnostic classification system, diagnosed according to one criterion, not specified), (20) additional diagnostic information (description of former treatments, diagnostic findings of physicians), (21) patient characteristics (means and standard deviations or range for age and years with migraine, percentage of female patients).

Treatment: (22) type of biofeedback intervention (TF, BVP-FB, EMG-FB, EEG, SCF), (23) additional relaxation training during biofeedback (yes, no), (24) feedback modality (visual, auditory, both, freely selectable, false feedback, not reported), (25) type of control intervention (waiting list, relaxation, cognitive therapy, placebo control, pharmacotherapy), (26) treatment setting (BFB without home training, BFB in combination with home training, home-based follow-up care), (27) treatment documentation (treatment manual, general information, not specified), (28) changes in medication (controlled, not specified).

Items of the validity framework:

Internal validity: (1) design (controlled vs. uncontrolled), (2) treatment allocation (randomized vs. quasi-randomized or not randomized), (3) number of

dropouts (<20% between pre and post measurement and <35% between pre and follow-up measurement vs. >20% between pre and post measurement and >35% between pre and follow-up measurement), (4) type of outcome variables (headache variables measured over equal time periods at pre, post, and follow-up measurement).

External validity: (5) measurement points (pre–post and follow-up vs. only pre–post), (6) patient characteristics (information on age, sex and headache history given vs. information missing in one or all categories).

Construct validity: (7) treatment documentation (treatment manual with number and duration of the treatment sessions given vs. no manual documented or missing information on number and duration of the treatment sessions), (8) diagnostic instruments (ICD or IHS vs. diagnosed without structured criteria), (9) changes in medication (controlled or valid solution vs. uncontrolled), (10) blinding (double or single blind vs. no blinding).

Statistical conclusion validity: (11) number of participants (>10 per treatment group vs. <10 per treatment group), (12) statistical data for the calculation of effect sizes (means and standard deviations reported vs. no means and standard deviations reported).

According to this framework, a study with maximum validity had to be a randomized controlled evaluation study with at least one follow-up measurement. There had to be more than 10 patients per treatment group and a dropout rate of less than 20% after assignment and less than 35% at follow-up. Patients had to be diagnosed with a structured diagnostic system and potential changes in their migraine medication during treatment adherence had to be controlled. Studies had to be conducted double blind or at least under control of patient expectancies. Study authors had to report treatment manuals as well as demographic variables of the patient sample. The treatment outcome had to be measured with at least one headache or one psychological variable reported in means and standard deviations for all measurement times and analysed with a focused research hypothesis.

References

**Indexed studies are included in the meta-analysis.*

Ad Hoc Committee on Classification of Headache: Classification of headache. *JAMA* 1962;179:717–8.

*Allen RA, Mills GK. The effects of unilateral plethysmographic feedback of temporal artery activity during migraine head pain. *J Psychosom Res* 1982;26:133–40.

Andrasik F, Walch SE. Headaches. In: Nezu AM, Nezu CM, Geller PA, editors. *Health psychology*. Weiner IB, editors. *Handbook of psychology* 2001;vol. 9. New Jersey: Wiley; 2001. p. 245–66.

*Andrasik F, Blanchard EB, Neff DF, Rodichok LD. Biofeedback and relaxation training for chronic headache: a controlled comparison

- of booster treatments and regular contacts for long-term maintenance. *J Consult Clin Psychol* 1984;52:609–15.
- Andrasik F, Lipchik GL, McCrory DC, Wittrock DA. Outcome measurement in behavioral headache research: headache parameters and psychosocial outcomes. *Headache* 2005;45:429–37.
- *Andreychuk T, Skriver C. Hypnosis and biofeedback in the treatment of migraine headache. *Int J Clin Exp Hypn* 1975;23:172–83.
- Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;276:637–9.
- *Bild R, Adams HE. Modification of migraine headaches by cephalic blood volume pulse and EMG biofeedback. *J Consult Clin Psychol* 1980;48:51–7.
- Blanchard EB. Long-term effects of behavioral treatment of chronic headache. *Behav Ther* 1987;18:375–85.
- Blanchard EB, Andrasik F. Biofeedback treatment of vascular headache. In: Hatch JP, Fisher JG, Rugh J, editors. *Biofeedback. Studies in clinical efficacy*. New York: Plenum Press; 1987. p. 1–49.
- *Blanchard EB, Kim M. The effect of the definition of menstrually-related headache on the response to biofeedback treatment. *Appl Psychophysiol Biofeedback* 2005;30:53–63.
- *Blanchard EB, Dale ET, Williamson DA, Silver BV, Brown DA. Temperature biofeedback in the treatment of migraine headaches: a controlled evaluation. *Arch Gen Psychiatry* 1978;35:581–8.
- Blanchard EB, Andrasik F, Ahles TA, Teders SJ, O'Keefe DM. Migraine and tension headache: a meta-analytic review. *Behav Ther* 1980;11:613–31.
- *Blanchard EB, Andrasik F, Neff DF, Arena JG, Ahles TA, Jurish SE, Pallmeyer TP, Saunders NL, Teders SJ. Biofeedback and relaxation training with three kinds of headache: treatment effects and their prediction. *J Consult Clin Psychol* 1982a;50:562–75.
- *Blanchard EB, Andrasik F, Neff DF, Teders SJ, Pallmeyer TP, Arena JG, Jurish SE, Saunders NL, Ahles TA, Rodichok LD. Sequential comparisons of relaxation training and biofeedback in the treatment of three kinds of chronic headache or, the machines may be necessary some of the time. *Behav Res Ther* 1982b;20:469–81.
- *Blanchard EB, Appelbaum KA, Guarnieri P, Neff DF, Andrasik F, Jaccard J, Barron KD. Two studies of the long-term follow-up of minimal therapist contact treatments of vascular and tension headache. *J Consult Clin Psychol* 1988;56:427–32.
- *Blanchard EB, Appelbaum KA, Nicholson NL, Radnitz CL, Morrill B, Michultka D, Kirsch C, Hillhouse J, Dentinger MP. A controlled evaluation of the addition of cognitive therapy to a home-based biofeedback and relaxation treatment of vascular headache. *Headache* 1990a;30:371–6.
- *Blanchard EB, Appelbaum KA, Radnitz CL, Morrill B, Michultka D, Kirsch C, Guarnieri P, Hillhouse J, Evans DD, Jaccard J. A controlled evaluation of thermal biofeedback and thermal biofeedback combined with cognitive therapy in the treatment of vascular headache. *J Consult Clin Psychol* 1990b;58:216–24.
- *Blanchard EB, Nicholson NL, Radnitz CL, Steffek BD, Appelbaum KAPDM, Dentinger MP. The role of home practice in thermal biofeedback. *J Consult Clin Psychol* 1991;59:507–12.
- *Blanchard EB, Kim M, Herman NC, Steffek BD, Nicholson NI, Taylor AE. The role of perception of success in the thermal biofeedback treatment of vascular headache. *Headache Q* 1994;5:231–6.
- *Blanchard EB, Peters ML, Hermann C, Turner SM, Buckley TC, Barton K, Dentinger MP. Direction of temperature control in the thermal biofeedback treatment of vascular headache. *Appl Psychophysiol Biofeedback* 1997;22:227–45.
- *Claghorn JL, Mathew RJ, Largen JW, Meyer JS. Directional effects of skin temperature self-regulation on regional cerebral blood flow in normal subjects and migraine patients. *Am J Psychiatry* 1981;138:1182–7.
- *Cohen MJ, McArthur DL, Rickles WH. Comparison of four biofeedback treatments for migraine headache: psychological and headache variables. *Psychosom Med* 1980;42:463–80.
- *Daly EJ, Donn PA, Galliher MJ, Zimmerman JS. Biofeedback applications of migraine and tension headaches: a double-blinded outcome study. *Biofeedback Self Regul* 1983;8:135–52.
- Devineni T, Blanchard EB. A randomized controlled trial of an Internet-based treatment for chronic headache. *Behav Res Ther* 2005;43:277–92.
- Eccleston C, Morley S, Williams A, Yorke L, Mastroyannopoulou K. Systematic review of randomized controlled trials of psychological therapy for chronic pain in children and adolescents, with a subset of meta-analysis pain relief. *Pain* 2002;99:157–65.
- *French DJ, Gauthier JG, Roberge C, Bouchard S, Nouwen A. Self-efficacy in the thermal biofeedback treatment of migraine sufferers. *Behav Ther* 1997;28:109–25.
- *Friar LR, Beatty J. Migraine: management by trained control of vasoconstriction. *J Consult Clin Psychol* 1976;44:46–53.
- *Gauthier JG, Carrier S. Long-term effects of biofeedback on migraine headache: a prospective follow-up study. *Headache* 1991;31:605–12.
- *Gauthier J, Bois R, Allaire D, Drolet M. Evaluation of skin temperature biofeedback training at two different sites for migraine. *J Behav Med* 1981;4:407–19.
- *Gauthier J, Doyon J, Lacroix R, Drolet M. Blood volume pulse biofeedback in the treatment of migraine headache: a controlled evaluation. *Biofeedback Self Regul* 1983;8:427–42.
- *Gauthier J, Lacroix R, Cote A, Doyon J, Drolet M. Biofeedback control of migraine headaches: a comparison of two approaches. *Biofeedback Self Regul* 1985;10:139–59.
- *Gauthier J, Fradet C, Roberge C. The differential effects of biofeedback in the treatment of classical and common migraine. *Headache* 1988;28:39–46.
- *Gauthier JG, Fournier AL, Roberge C. The differential effects of biofeedback in the treatment of menstrual and nonmenstrual migraine. *Headache* 1991;31:82–90.
- *Gauthier J, Cote G, French D. The role of home practice in the thermal biofeedback treatment of migraine headache. *J Consult Clin Psychol* 1994;62:180–4.
- Gibbons RD, Hedecker DR, Davis JM. Estimation of effect size from a series of experiments involving paired comparisons. *J Educ Stat* 1993;18:271–9.
- Glass GV. Primary, secondary and meta-analysis of research. *Educ Res* 1976;5:3–8.
- Gleser LJ, Olkin I. Stochastically dependent effect sizes. In: Cooper H, Hedges LV, editors. *Handbook of research synthesis*. New York: Russel Sage; 1994. p. 339–55.
- Goslin RE, Gray RN, McCrory DC, Penzien DB, Rains JC, Hasselblad V. Behavioral and physical treatments for migraine headache (Technical Review 2.2). Prepared for the Agency for Health Care Policy and Research under Contract No. 290-94-2025. (NTIS Accession No. 127946); 1999.
- *Grazzi L, Bussone G. Effect of biofeedback treatment on sympathetic function in common migraine and tension-type headache. *Cephalalgia* 1993a;13:197–200.
- *Grazzi L, Bussone G. Italian experience of electromyographic-biofeedback treatment of episodic common migraine: preliminary results. *Headache* 1993b;33:439–41.
- Haddock CK, Rowan AB, Andrasik F, Wilson PG, Talcott GW, Stein RJ. Home-based behavioral treatments for chronic benign headache: a meta-analysis of controlled trials. *Cephalalgia* 1997;17:113–8.
- Hartmann A, Herzog T. Varianten der Effektstärkenberechnung in Meta-Analysen: Kommt es zu variablen Ergebnissen? (Calculating effect size by varying formulas: are there varying results?). *Z Klin Psychol* 1995;24:337–43.

- Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalalgia* 1988;8:1–96.
- Hedges LV. Fixed effects models. In: Cooper H, Hedges LV, editors. *Handbook of research synthesis*. New York: Russel Sage; 1994. p. 285–99.
- Hedges LV, Olkin I. *Statistical methods for meta-analysis*. Orlando: Academic Press; 1985.
- Hedges LV, Vevea JL. Fixed- and random-effects models in meta-analysis. *Psychol Methods* 1998;3:485–504.
- Higgins JPT, Green S, editors. *Cochrane Handbook for systematic reviews of interventions 4.2.5 [updated May 2005]*, The Cochrane Library, Issue 3. Chichester: Wiley; 2005.
- Hobro N, Weinman J, Hankins M. Using the self-regulatory model to cluster chronic pain patients: the first step towards identifying relevant treatments? *Pain* 2004;108:276–83.
- Holroyd KA, Penzien DB. Pharmacological versus non-pharmacological prophylaxis of recurrent migraine headache: a meta-analytic review of clinical trials. *Pain* 1990;42:1–13.
- Holroyd KA, Penzien DB, Hursey KG, Tobin DL, Rogers L, Holm JE, et al. Change mechanisms in EMG biofeedback training: cognitive change underlying improvements in tension headache. *J Consult Clin Psychol* 1984;52:1039–53.
- *Holroyd KA, Holm JE, Hursey KG, Penzien DB, Cordingley GE, Theofanous A. Recurrent vascular headache: home-based behavioral treatment versus abortive pharmacological treatment. *J Consult Clin Psychol* 1988;56:218–23.
- *Holroyd KA, Holm JF, Penzien DB, Cordingley GE, Hursey KG, Martin NJ, et al. Long-term maintenance of improvements achieved with (abortive) pharmacological and nonpharmacological treatments for migraine: preliminary findings. *Biofeedback Self Regul* 1989;14:301–8.
- *Holroyd KA, France JL, Cordingley GE, Rokicki LA, Kvaal SA, Lipchik GL, McCool HR. Enhancing the effectiveness of relaxation-thermal biofeedback training with propranolol hydrochloride. *J Consult Clin Psychol* 1995;63:327–30.
- Houle TT, Penzien DB, Houle CK. Statistical power and sample size estimation for headache research: an overview and power calculation tools. *Headache* 2005;45:414–8.
- *Ilacqua GE. Migraine headaches: coping efficacy of guided imagery training. *Headache* 1994;34:99–102.
- International Headache Society Clinical Trials Subcommittee. Guidelines for controlled trials of drugs in migraine: second edition. *Cephalalgia* 2000;20:765–86.
- Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996;17:1–12.
- *Johansson J, Öst LG. Temperature-biofeedback treatment of migraine headache. Specific effects and the effects of “generalization training”. *Behav Modif* 1987;11:182–99.
- Johnson BT. *DSTST: software for the meta-analytical review of research literature*. Hillsdale: LEA; 1989.
- *Jurish SE, Blanchard EB, Andrasik F, Teders SJ, Neff DF, Arena JG. Home- versus clinic-based treatment of vascular headache. *J Consult Clin Psychol* 1983;51:743–51.
- *Kewman DM, Roberts AH. Skin temperature biofeedback and migraine headaches. A double-blind study. *Biofeedback Self Regul* 1980;327–45.
- *Kim M, Blanchard EB. Two studies of the non-pharmacological treatment of menstrually-related migraine headaches. *Headache* 1992;32:197–202.
- *Knapp TW, Florin I. The treatment of migraine headache by training in vasoconstriction of the temporal artery and a cognitive stress-coping training. *Behav Anal Modif* 1981;4:267–74.
- *Kroener B. Biofeedback als Interventionsverfahren bei chronischen Kopfschmerzen. (Biofeedback as an intervention procedure for chronic headaches). *Z Exp Angew Psychol* 1982;29:264–89.
- Kroener-Herwig B, Sachse R. *Biofeedback-Therapie*. Stuttgart: Kohlhammer; 1988.
- *Kropp P, Gerber WD, Keinath Specht A, Kopal T, Niederberger U. Behavioral treatment in migraine. Cognitive-behavioral therapy and blood-volume-pulse biofeedback: a cross-over study with a two-year followup. *Funct Neurol* 1997;12:17–24.
- Kropp P, Siniatchkin M, Gerber WD. On the pathophysiology of migraine – links for “empirically based treatment” with neurofeedback. *Appl Psychophysiol Biofeedback* 2002;27:203–13.
- *Lake A, Rainey J, Papsdorf JD. Biofeedback and rational-emotive therapy in the management of migraine headache. *J Appl Behav Analysis* 1979;12:127–40.
- *Largen JW, Mathew RJ, Dobbins K, Claghorn JL. Specific and non-specific effects of skin temperature control in migraine management. *Headache* 1981;21:36–44.
- Lipchik GL, Holroyd KA. Behavior therapy for headache. *Clin Psychol* 1999;52:3–5.
- Lipton RB, Stewart WF, Diamond S, Diamond ML, Reed M. Prevalence and burden of migraine in the United States: data from the American Migraine Study II. *Headache* 2001;41:646–57.
- Lipton RB, Bigal ME, Scheer AI, Stewart WF. The global burden of migraine. *J Headache Pain* 2003;4:3–11.
- *Lisspers J, Öst LG. Long-term follow-up of migraine treatment: do the effects remain up to six years? *Behav Res Ther* 1990;28:313–22.
- *Marcus DA, Scharff L, Mercer S, Turk DC. Nonpharmacological treatment for migraine: incremental utility of physical therapy with relaxation and thermal biofeedback. *Cephalalgia* 1998;18:266–72.
- McGaw B, Glass GV. Choice of the metric for effect size in meta-analysis. *Am Educ Res J* 1980;17:325–37.
- *McGrady A, Wauquier A, McNeil A, Gerard G. Effect of biofeedback-assisted relaxation on migraine headache and changes in cerebral blood flow velocity in the middle cerebral artery. *Headache* 1994;34:424–8.
- *Medina JL, Diamond S, Franklin MA. Biofeedback therapy for migraine. *Headache* 1976;16:115–8.
- *Mizener D, Thomas M, Billings RF. Cognitive changes of migraineurs receiving biofeedback training. *Headache* 1988;28:339–43.
- Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of reporting of meta-analyses. *Lancet* 1999;354:1896–900.
- Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191–4.
- Morris SB, DeShon RP. Combining effect size estimates in meta-analysis with repeated measures and independent-groups designs. *Psychol Methods* 2002;7:105–25.
- *Mullinix JM, Norton BJ, Hack S, Fishman MA. Skin temperature biofeedback and migraine. *Headache* 1978;17:242–4.
- Nash JM, McCrory D, Nicholson RA, Andrasik F. Efficacy and effectiveness approaches in behavioral treatment trials. *Headache* 2005;45:507–12.
- *Neff DF, Blanchard EB, Andrasik F. The relationship between capacity for absorption and chronic headache patients’ response to relaxation and biofeedback treatment. *Biofeedback Self Regul* 1983;8:177–83.
- *Nicholson NL, Blanchard EB. A controlled evaluation of behavioral treatment of chronic headache in the elderly. *Behav Ther* 1993;24:395–408.
- Oldman AD, Smith LA, McQuay HJ, Moore RA. Pharmacological treatments for acute migraine: quantitative systematic review. *Pain* 2002;97:247–57.

- Penzien DB, Holroyd KA, Holm JE, Hursey KG. Behavioral management of migraine: results from five-dozen group outcome studies. *Headache* 1985;25.
- Penzien DB, Rains JC, Lipchik GL, Nicholson RA, Lake AE, Hursey KG. Future directions in behavioral headache research: applications for an evolving health care environment. *Headache* 2005;45:526–34.
- Rains JC, Penzien DB, McCrory DC, Gray RN. Behavioral headache treatment: history, review of the empirical literature, and methodological critique. *Headache* 2005;45:92–109.
- Ray JW, Shadish WR. How interchangeable are different estimators of effect size? *J Consult Clin Psychol* 1996;64:1316–25.
- Rief W, Hofmann SG. The missing data problem in meta-analysis. *Arch Gen Psychiatry*; in press.
- Rosenthal R. The “file drawer problem” and tolerance for null results. *Psychol Bull* 1979;86:638–41.
- Rosenthal R. Parametric measures of effect size. In: Cooper H, Hedges LV, editors. *The handbook of research synthesis*. New York: Russel Sage; 1994. p. 231–44.
- Rowan AB, Andrasik F. Efficacy and cost-effectiveness of minimal therapist contact treatments for chronic headache: A review. *Behav Ther* 1996;27:207–34.
- *Sargent J, Solbach P, Coyne L, Spohn H, Segerson J. Results of a controlled, experimental, outcome study of nondrug treatments for the control of migraine headaches. *J Behav Med* 1986;9:291–323.
- Shadish WR, Haddock CK. Combining estimates of effect size. In: Cooper H, Hedges LV, editors. *The handbook of research synthesis*. New York: Russel Sage; 1994. p. 261–81.
- *Silver BV, Blanchard EB, Williamson DA, Dale ET, Brown DA. Temperature biofeedback and relaxation training in the treatment of migraine headaches: one-year follow-up. *Biofeedback Self Regul* 1979;4:359–66.
- Siniatchkin M, Hierundar A, Kropp P, Kuhnert R, Gerber WD, Stephani U. Self-regulation of slow cortical potentials in children with migraine: an exploratory study. *Appl Psychophysiol Biofeedback* 2000;25:13–32.
- Smith ML, Glass GV, Miller TI. *The benefits of psychotherapy*. London: John Hopkins; 1980.
- *Sorbi M, Tellegen B. Multimodal migraine treatment: does thermal feedback add to the outcome? *Headache* 1984;24:249–55.
- Steel PD, Kammeyer-Mueller JD. Comparing meta-analytic moderator estimation techniques under realistic conditions. *J Appl Psychol* 2002;87:96–111.
- Stovner LJ, Zwart JA, Hagen K, Terwindt GM, Pascual JP. Epidemiology of headache in Europe. *Eur J Neurol* 2006;13:333–45.
- *Turin A, Johnson WG. Biofeedback therapy for migraine headaches. *Arch Gen Psychiatry* 1976;33:517–9.
- *Vasudeva S, Claggett AL, Tietjen GE, McGrady AV. Biofeedback-assisted relaxation in migraine headache: relationship to cerebral blood flow velocity in the middle cerebral artery. *Headache* 2003;43:245–50.
- Wang MC, Bushmann BJ. Using the normal quantile plot to explore meta-analytic data sets. *Psychol Methods* 1998;3:46–54.
- *Wauquier A, McGrady A, Aloe L, Klausner T, Collins B. Changes in cerebral blood flow velocity associated with biofeedback-assisted relaxation treatment of migraine headaches are specific for the middle cerebral artery. *Headache* 1995;35:358–62.
- Wenzel RG, Lipton RB, Diamond ML, Cady R. Migraine therapy: a survey of pharmacists’ knowledge, attitudes, and practice patterns. *Headache* 2005;45:47–52.
- Wortmann PM. Judging research quality. In: Cooper H, Hedges LV, editors. *The handbook of research synthesis*. New York: Russel Sage; 1994. p. 97–109.
- Wright CC, Sim J. Intention-to-treat approach to data from randomized controlled trials: a sensitivity analysis. *J Clin Epidemiol* 2003;56:833–42.
- Yoon M, Savidou I, Diener H, Limmroth V. Evidence-based medicine in migraine prevention. *Expert Rev Neurother* 2005;5:333–41.