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Biofeedback Treatment for Headache Disorders: A Comprehensive Efficacy Review

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Abstract The aim of the present review was to critically evaluate the documented evidence regarding the efficacy of biofeedback for the two most prevalent headache conditions—migraine and tension-type headache. Drawing upon two recently published meta-analyses, data from 150 outcome studies, including randomized controlled trials as well as uncontrolled quasi-experimental designs, were screened. Of these, 94 studies were selected for inclusion according to predefined criteria. Meta-analytic integrations were carried out separately for the two conditions of interest. The main results were medium-to-large mean effect sizes for biofeedback in adult migraine and tension-type headache patients. Treatment effects remained stable over an average follow-up period of 14 months, both in completer and intention-to-treat analyses. Headache frequency was the primary outcome variable and showed the largest improvements. Further significant effects were shown for perceived self-efficacy, symptoms of anxiety and depression, and medication consumption. Reduced muscle tension in pain related areas was observed in electromyographic feedback for tension-type headache. Biofeedback was more effective than waiting list and headache monitoring conditions in all cases, while electromyographic feedback for tension-type headache showed additional significant effects over placebo and relaxation therapies. Levels of efficacy (migraine: efficacious, *level 4*; tension-type headache: efficacious and specific, *level 5*) and recommendations for future research are provided.

Keywords Migraine · Tension-type headache · Biofeedback · Relaxation · Treatment efficacy · Meta-analysis · White paper

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Migraine and tension-type headache (TTH) are the two most prevalent and disabling headache condition in adults (Rasmussen et al. 1991) as well as in children and adolescents (Kroener-Herwig et al. 2007). In North America migraine is experienced by 18% of women and 7% of men, with at least one attack per year (Lipton et al. 2001). The more common but less disabling episodic tension-type headache (ETTH) is estimated with a one-year prevalence of 38%, while the prevalence of chronic tension-type headache (CTTH), defined as having a frequency of at least

15 days per month, is estimated at 2–3% (Schwartz et al. 1998). Significant negative social and economic impacts resulting from these headache conditions have been reported (Stovner et al. 2007).

Headache patients frequently experience deteriorated functional levels at home, work and school (Molarius and Tegelberg 2006). Biofeedback treatments for pain emphasize the patients' active role in managing these conditions, thereby establishing improved coping with the psychological and psychosocial consequences of pain. For the treatment of headache, several different feedback modalities are being used, focussing on multiple psychophysiological parameters more or less directly assumed to underlie the condition. To enhance efficacy, biofeedback is often combined with relaxation and cognitive-behavioral elements such as stress management. The measurement of treatment success, therefore, mostly includes psychophysiological and behavioral variables in addition to the symptom-related ones. Taking this diversity of treatment applications, components, and outcome measures into account is one of the challenges of efficacy reviews today. This comprehensive review will offer an independent evaluation of the efficacy of biofeedback for headache, including moderating effects of feedback modalities, outcome categories, and trial design. Efficacy recommendations, according to the guidelines jointly established by the Association for Applied Psychophysiology and Biofeedback (AAPB) and the International Society for Neurofeedback and Research (ISNR), will be put forward.

Various biofeedback modalities are used for the treatment of both migraine and TTH, building upon different physiological and psychophysiological mechanisms that are assumed to be relevant for the conditions. In migraine, peripheral skin temperature feedback (TEMP-FB), blood-volume-pulse feedback (BVP-FB) and electromyographic feedback (EMG-FB) are the most prominent applications, while electroencephalographic feedback (EEG-FB) and galvanic skin response training (GSR-FB) are seldom used. The efficacy of biofeedback in treating migraine has been established in earlier reviews with improvement rates for pain from 40% to 65% (Blanchard and Andrasik 1987; Blanchard et al. 1980). Comparable treatment gains resulted for behavioral treatments and pharmacotherapies (Holroyd and Penzien 1990). In a more recent review medium effect sizes for EMG-FB and TEMP-FB in combination with relaxation have been reported (Goslin et al. 1999). While this was the first review providing standardized measures of treatment effect, the number of integrated studies was very small ($n = 11$) and confidence intervals for the resulting effects were rather broad. Also, analyses were limited to the two aforementioned feedback modalities, only post-treatment data were analysed, and no moderator analyses were performed. BVP-FB was excluded due to the technical difficulty in administering it. Further meta-analytic data integrations are needed to determine the short-term and long-term efficacy of BVP-FB and to establish treatment moderators for migraine.

The most frequently applied behavioral treatment option for TTH is EMG-FB, directed at reducing pericranial muscle activity. Previous quantitative reviews assessing the outcome of various behavioral treatments for TTH, including biofeedback, relaxation, cognitive therapy, and hypnotherapy (Blanchard et al. 1980; Bogaards and ter Kuile 1994; Haddock et al. 1997; Holroyd and Penzien 1986; McCrory et al. 2001) have shown average improvement rates for pain from 46% (Holroyd and Penzien 1986) to 61% (Blanchard et al. 1980), exceeding those of no-treatment conditions (Bogaards and ter Kuile 1994). Two meta-analyses investigating psychological headache treatments have provided standardized measures of treatment success for pain. McCrory et al. (2001) have reported medium-to-large average effects for EMG-FB in adults, while Trautmann et al. (2006) documented small-to-medium effect sizes for the efficacy of psychological headache treatments in children and adolescents. Specific comparisons of biofeedback for TTH to other behavioral headache treatments have not yet been meta-analytically integrated. Likewise the long-term effects of biofeedback for TTH, the efficacy on different outcome measures, and treatment moderators have not yet been systematically analysed. Notably, none of the previous reviews for migraine or TTH have integrated effect sizes for outcome variables other than headache or medication.

In the light of these limitations two recent meta-analyses have established scientifically sound evidence supporting the utility of biofeedback for migraine and TTH (Nestoriuc and Martin 2007; Nestoriuc et al. 2008). The objective of this comprehensive review is to present an up-to-date evaluation of the efficacy of biofeedback for headache. Drawing upon the two most recent meta-analyses in the field, evidence was incorporated, assessed, and documented according to the guidelines for the evaluation of the clinical efficacy of psychophysiological interventions (LaVaque et al. 2002). Analysed were the short- and long-term efficacy of biofeedback for migraine and TTH, treatment specificity, differential treatment effects in the form of pain measures, psychological, behavioral, and physiological outcome categories, as well as predictors of treatment success, such as patient characteristics and therapy features. Specific meta-analytic techniques were applied to control for possible confounding effects of selective publication, dropout, and study validity.

Methods

Definitions and Operationalizations

Condition of Interest

This biofeedback efficacy review covers two conditions of interest (COI), i.e., migraine and TTH. Diagnoses were based on a standardized classification system (i.e., IHS 2004; IHS 1988; Ad Hoc Classification System 1962) or an exact description of the disorder including characteristic features of migraine (i.e., severe pain, throbbing character, nausea, phono/photophobia or aura) or TTH (i.e., mild to moderate pain intensity, bilateral, nonpulsating quality, pressing or tightening, "band like" feeling, no exacerbation by exercise). Double diagnoses of TTH and migraine (mixed or combination headache) were excluded.

Types of Interventions

This review focussed on individually administered biofeedback treatments (TEMP-FB, EMG-FB, BVP-FB, EEG-FB, GSR-FB, or biofeedback in combination with other behavioral therapies).

Outcome Variables

Frequency of pain measured with a structured headache diary was considered the primary outcome variable for this review, as recommended by the International Headache Society (IHS 2000), the AHS Behavioral Clinical Trials Workgroup (Penzien et al. 2005), and Andrasik et al. (2005). Included as secondary outcome variables were intensity and duration of pain as well as headache and medication indices measured with headache diaries or pain scales, anxiety, depression, self-efficacy, and physiological parameters.

Study Inclusion Criteria

In addition to fulfilling the criteria mentioned before (COI, treatment, outcome) studies included in this review had to be published in English or German and report sufficient statistical data to allow the calculation of effect sizes. Excluded were studies with less than 4 patients per treatment arm and case studies.

Search Procedure

For the purpose of this review, the literature searches conducted in the two meta-analyses by Nestoriuc and Martin (2007) and Nestoriuc et al. (2008) were updated. We used three international and one German databases (Medline, PsycInfo, CENTRAL, and Psyndex from the first available year to March 2008) using the search terms *biofeedback* or *behavioral treatment* or *cognitive therapy* or *nonpharmacological* or *applied psychophysiology*. For the COI "migraine" these terms were paired with *migraine, vascular headache* or *mixed headache* and for "TTH" with *tension-type headache, muscle contraction headache, tension headache* or *chronic headache*. In addition to the formerly reviewed studies this search revealed 14 new studies, of which only two were treatment outcome studies. Five studies were reviews or meta-analyses, another five described treatment and assessment of headache conditions without evaluating them directly, and two were experimental investigations. Of the two outcome studies, one was included in the current review (Martin et al. 2007), the other one was excluded because no headache outcome variables were reported (Ciancarelli et al. 2007). Finally, a total of 94 studies met our criteria and were included this review (see Appendix A for a complete reference list of the studies integrated in this white paper).

Study Coding and Validity Assessment

For each study, clinical and methodological aspects were coded with a structured coding scheme, including a 12-item validity scale (see Appendix B for the Study Coding and Validity Assessment Scale). After training in the use of the coding system, all studies were coded by the first author and two independent reviewers (graduate students). A random sample of 20% of the migraine and all of the TTH studies were coded twice to establish reliability of the coding process. The reliability of the coding form as well as the interrater-agreement for the validity scale were proven satisfactory with mean reliability indices ranging from .84 to .91. The evaluation of the randomization procedure (e.g., randomized or quasi-randomized according to pre-existing criteria) or the therapy manual (e.g., provided manual or brief description of procedures) led to more disagreement than the coding of quantitative study aspects. Coding discrepancies were discussed and resolved.

Meta-analytic Procedures

Effect Size Calculation and Integration

Standardized effect sizes using Hedges' g (Hedges and Olkin 1985) for controlled trials and its pre-post equivalent for uncontrolled studies (Gibbons et al. 1993) were calculated for each outcome variable, treatment group and time point. The correction for small samples was applied (Hedges and Olkin 1985). Multiple effect sizes from a

single study were averaged with covariance adjustment prior to effect integration. Independent effect sizes were weighted by their individual sample size. Separate integrations were carried out with respect to different treatment comparisons, feedback modalities, outcome categories, and time points. Contingent with the homogeneity statistic Q (Shadish and Haddock 1994) fixed effect models or random effect models (REM) were applied to compute average effect sizes and confidence intervals. Moderating effects of patient, treatment, and study characteristics were tested with planned contrasts and weighted multiple regression analysis.

Sensitivity Analyses

Meta-analytic results can be biased due to the fact that studies with nonsignificant results are less likely to be published than those with significant results. This potential bias is called publication bias and can lead to an overestimation of treatment effects. To control for this bias, we calculated the number of studies with effect sizes of zero (i.e., fail-safe *n* rates) that would be needed to reduced the established average effect to insignificance (Rosenthal 1979). Intention-to-treat-analyses with a modified last-observation-carried-forward approach were applied to control for potential biases due to treatment dropout. Patients who dropped out of a study after treatment assignment were considered nonresponders and henceforth represented with zero effect sizes (i.e., no change in outcome variables). The individual completer effect sizes were corrected with those intention-to-treat effects within each study and then reintegrated.

Results

Characteristics of Included Studies

Included in this review were 94 studies, representing data from over 3,500 headache patients, that have been published between 1973 and 2007. Included in the meta-analysis of biofeedback for migraine were 56 studies with a mean of 40 patients per study. The meta-analysis on TTH consisted of 45 studies with a mean of 29 patients per study. In 7 of these studies treatment was provided for both migraine and TTH patients, and results were scored and presented independently. Key features of the integrated studies are presented in Table 1. Age means and gender distributions were similar for the two COI, with 37 and 38 years on average, and 88% and 73% percent women for Migraine and TTH, respectively. The TTH sample additionally included 9 studies investigating the efficacy of biofeedback for children and adolescents.[1] In the studies with adult headache patients, the average number of years since headache diagnosis was 17.1 for migraine and 14.8 for TTH. Diagnoses were made according to a standardized diagnostic system in 80% of the migraine studies and in 50% of the TTH studies. Unstandardized exams and interviews applying characteristic features of the two COI were used for diagnostic purposes in 7% of the migraine and in 34% of the TTH studies. In the remaining 13% of the migraine and 16% of the TTH studies patients' prior medical diagnoses were adopted from their records or interviews. During biofeedback treatment, 14% of the migraine and 8% of the TTH patients discontinued treatment. Information about attrition was provided in 76% of the migraine and 61% of the TTH studies. During follow-up, an additional 6% of migraine patients and 25% of the TTH patients ceased participation. Follow-up evaluations took place 14 months after treatment termination on average. In total, 136 active biofeedback conditions were investigated. For migraine, TEMP-FB in combination with either relaxation or EMG-FB, was the most frequently applied feedback modality, followed by TEMP-FB alone and BVP-FB. Seldom used were EMG-FB alone, EEG-FB and GSR-FB. For TTH, 92% of the biofeedback treatments were EMG-FB. Of these 16% were applied in combination with relaxation training. Other modalities were seldom used. In 80% of the EMG-FB treatments electrodes were placed bifrontal, in 12% multiple placements (i.e., frontal, neck or jaw) were used, and in 8% electrodes were placed on the neck. The number of biofeedback sessions ranged from 3 to 24 with an average of 11 sessions for both migraine and TTH. The duration of a treatment session ranged from 20 to 95 minutes, averaging 43 minutes for the two COI. In 78% of the migraine studies and 80% of the TTH studies treatment manuals were utilized and described in the publications. 78% of the integrated migraine studies and 58% of the TTH studies were conducted with control groups. The remaining 22% of the migraine studies and 42% of the TTH studies were uncontrolled pre-post evaluations. Within the controlled trials waiting list/no-treatment control groups were applied in 15 of the migraine and 8 of the TTH studies. Placebo control groups were applied in 12 of the migraine and 8 of the TTH studies. The placebo treatments were mostly pseudofeedback conditions, where patients were trained to influence psychophysiological parameter under false or stable feedback or in the opposite direction (e.g., increase of muscle tension). Active control treatments included relaxation training in 18% of the

[1] Studies with children and adolescents resulted in a significantly different average effect size (see Nestoriuc et al. 2008) and were therefore excluded from further analyses in this review. Hence, all results presented in this white paper review apply to adult headache patients.

Table 1 Characteristics of the integrated studies: demographics, diagnosis, treatment, validity

Characteristic	Migraine		TTH	
	n	Descriptive statistics	*n*	Descriptive statistics
Total number of patients	56	2266	45	1289
Age, mean (range)	46	37.2 (28–67)	38	37.9 (20–67)
Sex (% female, mean + range)	46	88.4 (21.2–100)	38	72.7 (42.9–100)
Years since diagnose, mean (range)	32	17.1 (8.5–37.6)	27	14.8 (3.0–42.4)
Use of standardized diagnostic system, %	45	80.4	23	51.0
Unstandardized exam (characteristic features)	4	7.2	15	34.1
Diagnose adopted from preceding medical exam	7	12.7	7	15.9
Dropout after treatment assignment, %	43	14.3	28	9.3
Dropout at follow-up, %	11	4.7	8	15.1
Duration of follow-up in month, mean (range)	16	14.3 (6–60)	17	14.0 (3–60)
Feedback modalities, number of treatment groups	56	85	45	51
EMG-FB		8		40
EMG-FB + relaxation/TEMP-FB		35		7
TEMP-BF		19		2
BVP-FB		16		–
EEG-FB		3		1
Galvanic skin response feedback		4		1
Number of sessions, mean (range)	56	10.8 (3–24)	45	11.2 (6–20)
Duration of sessions in minutes, mean (range)	45	43.5 (20–95)	41	42.6 (20–90)
Description of a treatment manual, %	44	78.6	36	80.0
Control conditions, number of groups	40	35	28	38
Waiting list		15		8
Placebo		12		8
Relaxation		5		14
Pharmacotherapy		2		3
CBT/Stress management		1		3
Physical treatment		–		2
Patient blinding, % calculated from controlled studies	10	25.6	6	22.2
Studies with $\geq$ 2 outcome categories, %	47	83.9	31	68.9
Outcome depicted in means and standard deviations, %	41	73.2	21	46.7

Note: Numbers are frequencies unless described otherwise. *N* = number of studies, TTH = tension-type headache, EEG-FB = Electroencephalographic feedback, EMG/FB = Electromyographic feedback, TEMP-FB = peripheral temperature feedback, RT = Relaxation training, BVP-FB = Blood-volume pulse feedback, CBT = cognitive behavioral therapy

migraine and 11% of the TTH studies. Within the controlled studies, 26% of the migraine and 22% of the TTH studies incorporated single or double-blind designs. Outcome was measured with headache parameters, and at least one other outcome category, in 84% of the migraine and 68% of the TTH studies. Means and standard deviations of the outcome variables that can be directly used for the calculation of effect sizes were presented in 73% of the migraine and 46% of the TTH studies.

Efficacy of Biofeedback in Controlled Trials

For the analysis of general efficacy, the variables headache frequency, duration, and intensity were integrated. These outcome variables were consistently measured with a structured headache diary in 92% of the migraine and 83% of the TTH studies. Mean weighted effect sizes[2] for all controlled comparisons are presented in Table 2. In the migraine studies, biofeedback yielded a significant small-to-medium effect size in comparison to waiting list control groups. An average small-to-medium effect size was found in comparison to placebo groups. However, this effect missed formal significance. A small non-significant effect

[2] Average effect sizes from .2 to .5 are considered small effects, average effect sizes from .5 to .8 are considered medium and average effects over .8 are considered large effects (Cohen 1988).

Table 2 Mean weighted effect sizes for headache reduction through biofeedback in different treatment comparisons

Comparison	Migraine			TTH		
	k	*n*	Effect size (95% CI)	*k*	*n*	Effect size (95% CI)
BFB versus no treatment control	15	591	0.46 (0.27, 0.64)	8	147	0.79 (0.40, 1.17)
BFB versus placebo control	12	340	0.25 (0.00, 0.49)	8	135	0.50 (0.26, 0.75)
BFB versus relaxation	5	136	0.10 (−0.39, 0.50)	14	396	0.18 (0.06, 0.30)

Note: BFB = biofeedback, Placebo = non-pharmacological placebo treatment (e. g., pseudo/sham feedback, finger cooling), TTH = tension type headache, *k* = number of effect sizes, *n* = number of headache patients, Effect Size = weighted mean effect size, 95% CI = confidence interval for mean effect size

in comparison to relaxation treatments was established. In the TTH studies, biofeedback yielded a significant medium-to-large effect size as compared to untreated control groups. A significant medium effect size was found in comparison to placebo control groups and a significant small effect size for biofeedback was obtained in comparison to relaxation control groups. For all reported comparisons, effect sizes were homogeneous according to the REM. The comparisons of biofeedback with pharmacotherapy, and physical and cognitive therapies, were insignificant and consisted of too few studies to provide reliable conclusions.

Efficacy in Pre-post and Follow-up Evaluations

Additional pre-post effect sizes were computed for all controlled and uncontrolled comparisons. Weighted mean effect sizes and confidence intervals for all pre-post and follow-up integrations are presented in Table 3. For migraine, 85 independent effect sizes ranging from −0.07 to 1.74 were computed. These effects were homogeneous in the fixed effect model. For all biofeedback modalities, a significant average effect size of medium magnitude resulted. This effect was proven to be robust in intention-to-treat analysis. Over 14 months follow-up, on average, a significant medium-to-large average effect size resulted. Reliability of the follow-up effects was established in the intention-to-treat analysis as well.

For TTH, the effect size calculation yielded 49 independent effect measures for headache relief from pre to post-treatment, ranging from 0.06 to 1.99. Effect size integration in the random effects model resulted in a significant large average effect size. In the intention-to-treat analysis, this effect size was shown to be reliable. Over an average 14 month follow-up, this effect was maintained and somewhat enhanced with an average medium-to-large effect size. Evaluation of the follow-up effect sizes in intention-to-treat analysis resulted in a significant medium-to-large average effect size.

Efficacy of Different Feedback Modalities for Migraine

Effect sizes with confidence intervals for the feedback modalities utilized in the biofeedback treatment of migraine are shown in Fig. 1. All feedback modalities showed significant effect sizes. The highest treatment gains resulted for BVP-FB, with an average medium-to-large effect size. An overall medium effect size resulted for TEMP-FB in combination with relaxation and EMG-FB, while small-to-medium effect sizes resulted for EMG-FB and TEMP-FB alone. Differences between the modalities were insignificant.

Table 3 Mean weighted effect sizes for headache reduction through biofeedback at post-treatment and follow-up in completer and intention-to-treat analyses

Comparison	Migraine			TTH		
	k	*n*	Effect size (95% CI)	*k*	*n*	Effect size (95% CI)
Pre versus post-treatment (Completer)	85	1489	0.58 (0.52, 0.65)	49	658	0.70 (0.57, 0.83)
Pre versus post-treatment (ITT)	85	1729	0.53 (0.45, 0.60)	49	712	0.59 (0.49, 0.70)
Pre-treatment versus follow-up (Completer)	25	475	0.67 (0.55, 0.79)	17	236	0.45 (0.28, 0.61)
Pre-treatment versus follow-up (ITT)	25	503	0.65 (0.47, 0.81)	17	313	0.31 (0.11, 0.45)

Note: BFB = biofeedback, TTH = tension type headache, *k* = number of effect sizes, *N* = number of headache patients, Effect Size = weighted mean effect size, 95% CI = confidence interval for mean effect size, ITT = intention-to-treat analysis. For ITT dropouts were considered as nonresponders and replaced with zero effects. Mean duration of follow-up for migraine studies is 14.3 (SD = 14.2) months, for TTH studies 14.0 (SD = 16.1) months

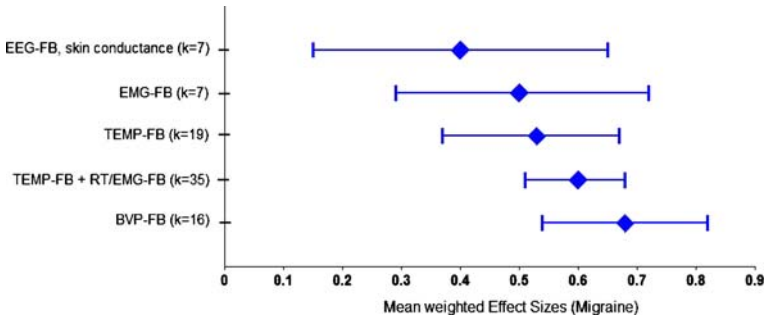

Fig. 1 Mean weighted effect sizes for the different feedback modalities in the treatment of migraine. Outcome is measured in headache pain. Mean effect sized are displayed with their individual 95% confidence intervals (k = number of independent effect sizes). EEG-FB = Electroencephalographic feedback, EMG/FB = Electromyographic feedback, TEMP-FB = peripheral temperature feedback, RT = Relaxation training, BVP-FB = Blood-volume pulse feedback

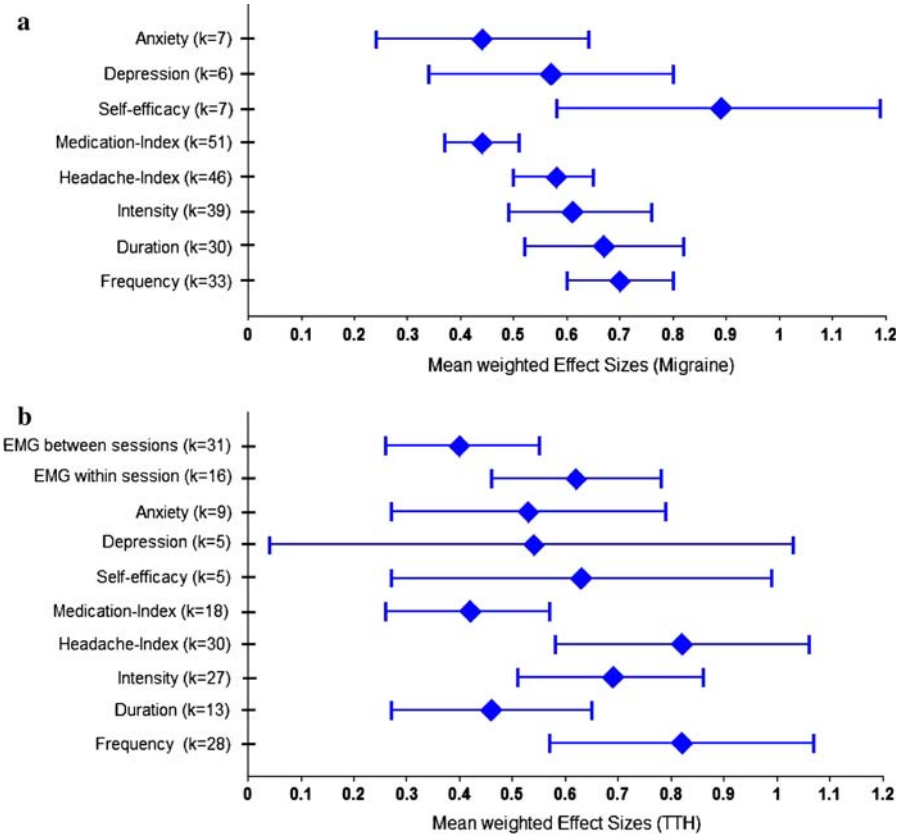

Fig. 2 (**a**) Mean weighted effect sizes for the different outcome variables in the biofeedback treatment of migraine. Outcome is measured in headache pain over all biofeedback modalities. Mean effect sized are displayed with their individual 95% confidence intervals (k = number of independent effect sizes). (**b**) Mean weighted effect sizes for the different outcome variables in EMG-FB for tension-type headache. Outcome is measured in headache pain. Mean effect sized are displayed with their individual 95% confidence intervals (k = number of independent effect sizes). EMG = reduction in muscle tension measured in microvolt through electromyography

Effects of Biofeedback on Different Types of Outcome Variables

Weighted average effect sizes and confidence intervals for all outcome variables are depicted in Fig. 2a for the migraine studies and in Fig. 2b for the TTH studies. In migraine, frequency, intensity, duration, and the headache-index were all reduced with significant medium effect sizes. Differences between these outcome categories were insignificant. For medication consumption, a small-to-medium effect size resulted. This effect was significantly smaller than the reduction on headache frequency and duration. Significant stronger improvements were shown for self-efficacy. Here a significant medium-to-large effect size resulted. Depression and anxiety showed medium effects, with confidence intervals ranging from small to large.

In the TTH studies, headache frequency, intensity, and the headache-index were reduced with large average effect sizes. Duration of headache episodes was reduced with a small-to-medium effect size. Physiological outcome (i.e., muscle tension in microvolts) was assessed as changes in muscle tension from baseline to post-treatment, and in

some studies, additional within-session changes were reported. Muscle tension was reduced with a significant medium-to-large effect size within treatment sessions and with a significant small effect size (confidence interval including medium effects) across sessions. Over the course of all biofeedback sessions, reductions in headache-index and frequency were significantly larger than the reductions in muscle tension. Self-efficacy, anxiety, and depression all yielded significant medium effect sizes, with corresponding confidence intervals ranging from small to large effect sizes. Medication intake was reduced with a significant small-to-medium effect size. The average effect size for headache-index was significantly higher than the effect size for medication intake. The other symptom categories did not show any significant differences.

Publication Bias

In addition to the graphical method (see funnel plots in Nestoriuc and Martin 2007), we examined publication bias by calculating fail-safe *ks* for the critical effect sizes 0.01 and 0.20. For migraine and TTH over 4,000 unpublished studies with zero effects would be necessary to reduce the observed average effect to zero. For a reduction to an average effect size of small magnitude (0.20) 148 migraine and 168 TTH studies with zero effects would be required. In sum, publication bias seems rather unlikely.

Discussion

This white paper review provides an up-to date evaluation of the efficacy of biofeedback as a behavioral treatment option for headache. The integration of 102 studies with over 140 active biofeedback treatment conditions allows us to draw generalizable conclusions regarding the efficacy of biofeedback. Depicted are data from over 3,500 headache patients with an average chronicity of migraine and TTH of over 14 years. The results apply for adult and geriatric headache patients.

General Efficacy and Specificity

Overall robust treatment effects of medium magnitude were established for migraine and TTH respectively. Effects are clinically meaningful as they demonstrate symptom improvements of over half a standard deviation for migraine and almost one standard deviation for patients suffering from TTH. The high chronicity of the sample with over 14 years of headache on average further supports the clinical significance of these results. With an overall average of 11 sessions biofeedback treatments were altogether short and economical. Furthermore, the treatment was generally very well accepted, as shown in the low dropout rates.

For migraine, a medium average effect size resulted for biofeedback in comparison to untreated control groups. This effect size corresponds with symptom improvements in headache scores exceeding those of 61% of the patients in the untreated control groups (Rosenthal and Rubin 1982). As indicated by the confidence interval, migraine patients treated with biofeedback will likely experience symptom improvements of 56–65% over and above those of an average patient in a waiting list control group. Although a small effect size for biofeedback in comparison to placebo was found, biofeedback treatment gains were not reliably higher than improvements in placebo feedback groups (i.e., psychological placebo for biofeedback including TEMP-FB with finger cooling). The average effect size found in comparison to placebo groups corresponds to a 56% success rate in biofeedback compared to 44% (38–50%) improvement in the placebo groups. Likewise differences between biofeedback and relaxation showed no significance in migraine. Thus, there is strong evidence for the efficacy, but only weak evidence for the treatment specificity of biofeedback in migraine.

In TTH a large average effect size resulted for EMG-FB in comparison to untreated control groups. This effect corresponds with a 69% success rate under biofeedback as opposed to a 31% (25–37%) chance of improvement in the untreated control groups. Superior clinical results also emerged for biofeedback compared to placebo control groups and relaxation therapies. The effect size over placebo was robust and of medium magnitude, corresponding with a 62% success rate versus 38% (34–43%) in the placebo groups. Similar improvement rates for medication placebo were documented by Blanchard, Andrasik et al. (1980). However, the improvements in placebo groups seemed to be higher in migraine than in TTH patients. The effect size over relaxation was small but reliable, corresponding with a 55% success rate versus 45% (42–48%) in the relaxation groups. Strong evidence regarding the efficacy as well as the specificity of biofeedback for TTH can be drawn from these results. Further efficacy comparisons of biofeedback to pharmacotherapy, physical therapy and cognitive therapy included only very few studies and cannot be interpreted reliably at this point.

Results of previous reviews have consistently shown biofeedback to be more effective than headache monitoring (Blanchard et al. 1980; Bogaards and ter Kuile 1994; Holroyd and Penzien 1986; McCrory et al. 2001), but were inconclusive about the specificity of biofeedback. Blanchard et al. (1980) pointed out nearly 30 years ago that there were too few studies to draw conclusions about the equivalence of alternative headache treatments. Holroyd and Penzien (1986) reported significant differences

between behavioral treatments and placebo conditions, but no differences within the active treatments. Until today, many studies have reported conflicting results with respect to the comparative efficacy of biofeedback and relaxation training, mostly due to underpowered statistical analyses (Houle et al. 2005). The results of this review point to a comparable efficacy of biofeedback and relaxation therapy in the case of migraine and to a superiority of biofeedback over relaxation in the treatment of TTH.

The efficacy findings from controlled comparisons were subsequently replicated in pre-post treatment comparisons. All available outcome data from the integrated randomized controlled as well as uncontrolled studies were included in the pre-post treatment comparisons. Robust medium average effect sizes resulted for the two COI, with a confidence interval including large effects for TTH. This review is the first to include intention-to-treat analyses for efficacy evaluations in behavioral headache treatments. The inclusion of all patients who dropped out of the active biofeedback groups during treatment resulted in slightly diminished but still significant medium average effect sizes for migraine and TTH. These results point to the robustness and clinical meaningfulness of the established effects, even when dropouts are considered as nonresponders.

Maintenance of Biofeedback Effects Over Time

In follow-up evaluations, the established effects were shown to persist up to several years after treatment. One study showed this to be the case whether additional treatment, in the form of booster sessions, was provided or not (Andrasik et al. 1984). The average medium effect sizes remained stable over follow-up intervals of 15 months for migraine and TTH. Supporting prior results (Blanchard et al. 1980) indicating the stability of biofeedback treatment gains, the presented results constitute the most comprehensive meta-analytical confirmation of the long-term efficacy of biofeedback for headache disorders. Intention-to-treat analysis showed that the established follow-up effects persisted even when dropouts were considered as nonresponders.

Moderating Effects of Different Feedback Modalities and Outcome Measures

The frequently applied feedback modalities in migraine all showed comparable treatment effects with reasonable confidence. The rarely investigated applications resulted in medium effects as well but produced less stable results. Among these, EEG-FB was applied in three studies only, showing small and medium effect sizes. Due to the small number of integrated studies, it is not possible to draw final conclusions regarding the efficacy of EEG-FB for migraine. It is both interesting and important to note that BVP-FB, a modality that has been excluded from prior efficacy reviews (Goslin et al. 1999), showed the highest improvement rates; effect sizes ranged into large effects. In TTH a differential analysis of feedback modalities is not necessary, as the majority of studies used EMG-Feedback.

With respect to the different outcome variables that have been evaluated, reliable effect sizes occurred for all headache variables. Headache frequency, the primary outcome variable, yielded the highest treatment effects in migraine and TTH. Also, consistently over both COI, the reduction in medication consumption, though robustly present, yielded the lowest effect sizes. In migraine, cognitive aspects, as measured with changes in self-efficacy, yielded higher effect sizes than the other outcomes. In TTH, the reductions in muscle tension as a measure of physiological outcome yielded similarly high effect sizes to the cognitive variables. Anxiety and depression were less often evaluated, resulting in rather imprecise estimated effects. It has to be noted that these results cannot be used to analyze treatment mediators, because the incorporated effect measures are only based on pre-and post-treatment assessment. It is highly recommended to incorporate mediator analyses in future headache trials (Penzien et al. 2005) in order to gain further insight into treatment mechanisms. Promising variables in that respect are self-efficacy and physiological changes, as well as comorbid reductions in depression and anxiety. There are some additional behavioral and socioecomic outcome categories that have seldom been assessed in the current headache trials (i.e., lost work days, health service use, general activity level, social and role functioning). Thus, in future studies we recommend incorporating direct measures of the functional, social, and socioeconomic burden of headache (Andrasik 2001; Andrasik et al. 2005).

Influence of Treatment Features, Patient Characteristics, and Study Validity

Analyses of treatment moderators are used to derive recommendations for the clinical utility of treatments. Our moderator analyses in the two recently published meta-analyses on migraine and TTH have established important treatment moderators, which we will briefly describe in the following section.

In the biofeedback treatment of migraine, home training was shown to be an essential component of the efficacy and maintenance of treatment benefits. Treatment manuals incorporating home training led to nearly 20% higher treatment effects for headache reduction. Surprisingly, headache chronicity turned out to be a positive treatment predictor both in adult migraine and TTH patients. This effect accounted for over 20% of the variability in the TTH effect sizes and turned out to be a significant predictor for

direct treatment efficacy and follow-up effects in migraine. It might be partly due to particularly high effects in geriatric headache patients (Nicholson and Blanchard 1993). However, the fact that more years with headache can lead to higher treatment benefits emphasizes the treatment possibilities inherent in biofeedback.

In the treatment of TTH, the combination of biofeedback with relaxation training, and the use of biofeedback alone can be recommended, especially for juvenile headache patients. No moderating effects were found for different training sites within the EMG-FB treatments, for study setting (i.e., outpatient versus including home training), treatment duration, or the diagnostic distinctions between CTTH, ETTH, and TTH with pericranial tenderness. Diagnostic distinctions between ETTH and the clinically more meaningful CTTH were only seldom made. Hence it is not yet possible to draw reliable conclusions regarding the equal effectiveness of EMG-FB for both headache conditions. Further studies directly comparing the efficacy of EMG-FB for episodic and chronic TTH are needed.

The validity levels of the integrated studies were uncorrelated with the treatment effects for both COI at post-treatment. Nevertheless, some validity issues seem present in the field of biofeedback (Yucha 2002). In some of the studies evaluated in this review, low sample sizes, resulting in power problems, failure to describe basic treatment and patient characteristics, as well as the use of unstructured diagnostic systems had a negative impact on validity levels. A number of excellent suggestions and recommendations concerning behavioral headache research have recently been put forward (Houle et al. 2005; Penzien et al. 2005; Rains et al. 2005), and future studies would undoubtedly benefit from adopting these standards.

Levels of Evidence of Efficacy

The evidence collected and presented in this comprehensive efficacy review leads to the conclusion that biofeedback for migraine can be supported as an efficacious treatment option. This constitutes *Level 4* evidence according to the AAPB/ISNR criteria (LaVaque et al. 2002). Efficacy comparisons to no-treatment control groups favoring biofeedback exist in studies from multiple independent research teams, using clearly defined diagnostic criteria and outcome measures as well as appropriate data analysis.

Biofeedback for TTH can be supported as an efficacious and specific treatment option. According to the AAPB/ISNR criteria this constitutes the highest level of evidence (*Level 5*), reserved for psychophysiological interventions, that have established *Level 4* evidence and have shown additional superior treatment results in comparisons to credible sham therapy or alternative bona fide treatments.

Appendix A

List of studies included in the efficacy review (* Indexed studies are included in both meta-analyses for migraine and TTH).

Allen, R. A., Mills, G. K. (1982). The effects of unilateral plethysmographic feedback of temporal artery activity during migraine head pain. *Journal of Psychosomatic Research*, 26(2):133–140.

Andrasik, F., Blanchard, E. B., Neff, D. F., Rodichok, L. D. (1984). Biofeedback and relaxation training for chronic headache: a controlled comparison of booster treatments and regular contacts for long-term maintenance. *Journal of Consulting and Clinical Psychology,* 52(4):609–615.

Andrasik, F. & Holroyd, K. A. (1980). A test of specific and nonspecific effects in the biofeedback treatment of tension headache. *Journal of Consulting and Clinical Psychology, 48(5),* 575–586.

Andrasik, F. & Holroyd, K. A. (1983). Specific and nonspecific effects in the biofeedback treatment of tension headache: 3-Year follow-up. *Journal of Consulting and Clinical Psychology, 51(4),* 634–636.

Andreychuk, T., Skriver, C. (19175) Hypnosis and biofeedback in the treatment of migraine headache. *International Journal of Clinlinical and Experimental Hypnosis*, 23(3):172–183.

Arena, J. G., Bruno, G. M., Hannah, S. L. & Meador, K. J. (1995). A comparison of frontal electromyographic biofeedback training, trapezius electromyographic biofeedback training, and progressive muscle relaxation therapy in the treatment of tension headache. *Headache, 35(7),* 411–419.

Arena, J. G., Hannah, S. L., Bruno, G. M. & Meador, K. J. (1991). Electromyographic biofeedback training for tension headache in the elderly: A prospective study. *Biofeedback and Self Regulation, 16(4),* 379–390.

Arndorfer, R. E. & Allen, K. D. (2001). Extending the efficacy of a thermal biofeedback treatment package to the management of tension-type headaches in children. *Headache, 41,* 183–192.

Bild, R., & Adams, H. E. (1980). Modification of migraine headaches by cephalic blood volume pulse and EMG biofeedback. *Journal of Consulting and Clinical Psychology,* 48(1):51–57.

Billings, R. F., Thomas, M. R., Rapp, M. S., Reyes, E. & Leith, M. (1984). Differential efficacy of biofeedback in headache. *Headache, 24(4),* 211–215.

Bischoff, C. & Dahlinger, E. (1993). Behandlung von Spannungskopfschmerz mit EMG -Biofeedback im Feld–ein Effizienzvergleich mit traditionellem EMG-Biofeedback. [Treatment of tension-type headache with

EMG-feedback in the field- Comparative efficacy to traditional EMG-feedback.] *Verhaltenstherapie, 3(4),* 286–295.

*Blanchard, E. B., Andrasik, F., Neff, D. F., Arena, J. G., Ahles, T. A., Jurish, S. E., Pallmeyer, T. P., Saunders, N. L., & Teders, S. J. (1982a). Biofeedback and relaxation training with three kinds of headache: Treatment effects and their prediction. *Journal of Consulting and Clinical Psychology,* 50(4):562–575.

*Blanchard, E. B., Andrasik, F., Neff, D. F., Teders, S. J., Pallmeyer, T. P., Arena, J. G., Jurish, S. E., Saunders, N. L., Ahles, T. A., & Rodichok, L. D. (1982b). 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. *Behavior Research and Therapy*, 20(5):469–481.

Blanchard, E. B., Appelbaum, K. A., Guarnieri, P. & Morrill, B. (1987). Five year prospective follow-up on the treatment of chronic headache with biofeedback and/or relaxation. *Headache, 27(10),* 580–583.

Blanchard, E. B., Appelbaum, K. A., Guarnieri, P., Neff, D. F., Andrasik, F., Jaccard, J., & Barron, K. D. (1988). Two studies of the long-term follow-up of minimal therapist contact treatments of vascular and tension headache. *Journal of Consulting and Clinical Psychology,* 56(3):427–432.

Blanchard, E. B., Appelbaum, K. A., Nicholson, N. L., Radnitz, C. L., Morrill, B., Michultka, D., Kirsch, C., Hillhouse, J., & Dentinger, M. P. (1990a). A controlled evaluation of the addition of cognitive therapy to a home-based biofeedback and relaxation treatment of vascular headache. *Headache,* 30(6):371–376.

Blanchard, E. B., Appelbaum, K. A., Radnitz, C. L., Morrill, B., Michultka, D., Kirsch, C., Guarnieri, P., Hillhouse, J., Evans, D. D., & Jaccard, J. (1990b). A controlled evaluation of thermal biofeedback and thermal biofeedback combined with cognitive therapy in the treatment of vascular headache. *Journal of Consulting and Clinical Psychology,* 58(2):216–224.

Blanchard, E. B., Dale, E. T., Williamson, D. A., Silver, B.·V., & Brown, D. A. (1978). Temperature biofeedback in the treatment of migraine headaches: A controlled evaluation. *Archives of General Psychiatry*, 35(5):581–588.

Blanchard, E. B., & Kim, M. (2005). The effect of the definition of menstrually-related headache on the response to biofeedback treatment. *Applied Psychophysiology and Biofeedback,* 30(1):53–63.

Blanchard, E. B., Kim, M., Herman, N.·C., Steffek, B. D., Nicholson, N.·I., & Taylor, A. E. (1994). The role of perception of success in the thermal biofeedback treatment of vascular headache. *Headache Quarterly,* 5(4):231–236.

Blanchard, E. B., Nicholson, N. L., Radnitz, C. L., Steffek, B. D., Appelbaum, K. A., & Dentonger, M. P. (1991). The role of home practice in thermal biofeedback. *Journal of Consulting and Clinical Psychology,* 59(4):507–512.

Blanchard, E. B., Peters, M. L., Hermann, C., Turner, S. M., Buckley, T. C., Barton, K., & Dentinger, M. P. (1997). Direction of temperature control in the thermal biofeedback treatment of vascular headache. *Applied Psychophysiology and Biofeedback,* 22(4):227–245.

Borgeat, F., Elie, R. & Castonguay, L. G. (1991). Muscular response to the therapist and symptomatic improvement during biofeedback for tension headache. *Biofeedback and Self Regulation, 16(2),* 147–155.

Borgeat, F., Elie, R. & Larouche, L. M. (1985). Pain response to voluntary muscle tension increases and biofeedback efficacy in tension headache. *Headache, 25(7),* 387–391.

Borgeat, F., Hade, B., Larouche, L. M. & Gauthier, B. (1984). Psychophysiological effects of therapist's active presence during biofeedback as a simple psychotherapeutic situation. *Psychiatric Journal of the University of Ottawa, 9(3),* 132–137.

Bruhn, P., Olesen, J. & Melgaard, B. (1979). Controlled trial of EMG feedback in muscle contraction headache. *Annals of Neurology, 6(1),* 34–36.

Budzynski, T. H., Stoyva, J. M., Adler, C. S. & Mullaney, D. J. (1973). EMG biofeedback and tension headache: A controlled outcome study. *Psychosomatic Medicine, 35(6),* 484–496.

Bussone, G., Grazzi, L., D'Amico, D., Leone, M. & Andrasik, F. (1998). Biofeedback-assisted relaxation training for young adolescents with tension-type headache: a controlled study. *Cephalalgia, 18(7),* 463–467.

Chesney, M. A. & Shelton, J. L. (1976). A comparison of muscle relaxation and electromyogram biofeedback treatments for muscle contraction headache. *Journal of Behavior Therapy and Experimental Psychiatry, 7(3),* 221–225.

Claghorn, J. L., Mathew, R. J., Largen, J. W., & Meyer, J. S. (1981). Directional effects of skin temperature self-regulation on regional cerebral blood flow in normal subjects and migraine patients. *American Journal of Psychiatry*, 138(9):1182–1187.

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Epstein, L. H. & Abel, G. G. (1977). An analysis of biofeedback training effects for tension headache patients. *Behavior Therapy, 8(1),* 37–47.

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*Grazzi, L., & Bussone, G. (1993a). Effect of biofeedback treatment on sympathetic function in common migraine and tension-type headache. *Cephalalgia*, 13(3):197–200.

Grazzi, L., & Bussone, G. (1993b). Italian experience of electromyographic-biofeedback treatment of episodic common migraine: preliminary results. *Headache*, 33(8):439–441.

Grazzi, L., D'Amico, D. & Bussone, G. (1992). Italian experience of electromyographic-biofeedback for tension headache: Clinical results and one-year follow-up. *Headache Quarterly, 3(4),* 421–425.

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McGrady, A., Wauquier, A., McNeil, A., & Gerard, G. (1994). Effect of biofeedback-assisted relaxation on migraine headache and changes in cerebral blood flow velocity in the middle cerebral artery. *Headache*, 34(7):424–428.

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Mizener, D., Thomas, M., & Billings, R. F. (1988). Cognitive changes of migraineurs receiving biofeedback training. *Headache*, 28(5):339–343.
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*Neff, D. F., Blanchard, E. B. & Andrasik, F. (1983). The relationship between capacity for absorption and chronic headache patients' response to relaxation and biofeedback treatment. *Biofeedback and Self Regulation, 8(1),* 177–183.
*Nicholson, N. L. & Blanchard, E. B. (1993). A controlled evaluation of behavioral treatment of chronic headache in the elderly. *Behavior Therapy, 24(3),* 395–408.
Paiva, T., Nunes, J. S., Moreira, A., Santos, J., Teixeira, J. & Barbosa, A. (1982). Effects of frontalis EMG biofeedback and diazepam in the treatment of tension headache. *Headache, 22(5),* 216–220.
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Appendix B

Study Coding Scheme

Identification: Identification number, coder, author, country, publishing journal, year of publication; *Methodology:* design, number of BFB and control groups, measurement points, type of outcome variables, use of a structured headache diary, number of weeks of diary assessment at pre, post and follow-up measurement, number of participants, number of dropouts, research hypothesis, statistical data for the calculation of effect sizes; *Subjects:* diagnosis, diagnostic instruments, additional diagnostic information, patient characteristics (age, years with headache, gender); *Treatment:* type of biofeedback intervention, additional relaxation training during biofeedback, feedback modality, type of control intervention, treatment setting, treatment documentation (number and duration of sessions, treatment manual), changes in medication.

Validity Assessment Scale

Internal Validity: Design, treatment allocation, dropout, type of outcome variables; *External validity:* time points, patient characteristics; *Construct validity:* treatment documentation, diagnose, medication status, blinding; *Statistical conclusion validity:* number of participants, statistics for effect size calculation.

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