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Randomized controlled trials of psychological therapies for management of chronic pain in children and adolescents: an updated meta-analytic review

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Abstract

The purpose of this meta-analytic review was to quantify the effects of psychological therapies for the management of chronic pain in youth. Specifically, in this review we updated previous systematic reviews of randomized controlled trials by including new trials, and by adding disability and emotional functioning to pain as treatment outcomes. Electronic searches of the Cochrane Register of Randomised Controlled Trials, MEDLINE, PsycLIT, EMBASE, and the Social Sciences Citation Index were conducted from inception through August 2008. Methodological quality of the studies was assessed, and data extracted on the three primary outcomes of interest. Twenty-five trials including 1247 young people met inclusion criteria and were included in the meta-analysis. Meta-analytic findings demonstrated a large positive effect of psychological intervention on pain reduction at immediate post-treatment and follow-up in youth with headache, abdominal pain, and fibromyalgia. Small and non-significant effects were found for improvements in disability and emotional functioning, although there were limited data on these outcomes available in the included studies. Omnibus cognitive-behavioral therapy, relaxation therapy, and biofeedback all produced significant and positive effects on pain reduction. Studies directly comparing the effects of self-administered versus therapist-administered interventions found similar effects on pain reduction. Psychological therapies result in improvement in pain relief across several different pain conditions in children. Future trials are needed that incorporate non-pain outcome domains, that focus significant therapeutic content on reductions in disability, and that include extended follow up to better understand maintenance of treatment effects.

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Keywords

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1. Introduction

Chronic pain affects 15–30% of children and adolescents[36;37;39], and results in a measurable decline in children's overall quality of life[31]. Many children with chronic pain experience significant pain-related disability such as limited social and physical activities and frequent school absences[20;21]. Children may also report higher levels of distress, anxiety and depression[9;31]. Moreover, children are at risk for continuing into adulthood with chronic pain, physical symptoms, and psychological problems[7]. Consequently, effective treatment in childhood may also lessen the economic and social impact of chronic pain in adulthood. Psychological interventions for children with chronic pain are a promising modality demonstrated to be effective in decreasing pain intensity[5].

To date, the primary psychological interventions evaluated in youth with chronic pain are behavioral, cognitive, and cognitive-behavioral interventions (CBT) using strategies such as relaxation training, biofeedback, and parental operant strategies[6]. Most of this treatment literature has focused on children with headache[16], although effective treatments have also been developed for children with abdominal, musculoskeletal, and disease-related pain[17; 19;41].

Several meta-analytic reviews using data pooling methods have documented the efficacy of psychological therapies for children with chronic pain. Eccleston et al.[5] found that psychological treatments were effective in reducing pain in children with chronic pain (primarily headache). The odds ratio for clinically significant reduction in pain (defined at 50%) was 9.62 and the number needed to treat was 2.32. In their review of pediatric migraine, Hermann and colleagues[13] found that biofeedback and relaxation were more effective than placebo treatments and prophylactic drug treatments in controlling headache. More recently, Trautmann et al.[40] found that psychological interventions for children with recurrent headache produced higher rates of clinically significant reductions in pain compared to the control conditions.

However, there remain several gaps in the literature due to shared limitations among the reviews that have used data pooling techniques. Treatment outcomes were confined to pain intensity and relevant non-pain outcomes such as mood or disability were not examined. In addition, all three meta-analyses focused almost exclusively on youth with headache. While Eccleston et al.'s review[5] aimed to include a range of pain conditions, twelve of thirteen studies included in the meta-analysis were interventions for children with head pain. Therefore, data pooling techniques have not been used for RCTs of psychological interventions for children with other chronic pain conditions.

In the last decade there has been an increase in psychological interventions for youth with chronic pain, and an updated meta-analytic review of treatment studies is warranted. The aims of this review were to update and expand upon previous reviews by including new trials of psychological treatments for youth with chronic pain, and to examine the efficacy of psychological interventions in not only decreasing pain intensity but also in improving emotional and physical functioning in children. In addition, we examined the relationship of various characteristics and methodological factors (e.g., intervention type, chronic pain

condition) on effect sizes related to treatment outcomes. We also sought to determine the overall quality of trials and its relationship to study outcomes.

2. Methods

2.1. Literature search strategy

A comprehensive literature search was conducted using the Cochrane Register of Randomised Controlled Trials, MEDLINE, PsycLIT, EMBASE, PubMed, and the Social Sciences Citation Index in order to identify randomized controlled trials (RCTs) of psychological treatments of chronic pain in children. Search dates were from inception of these databases to August 2008. RCTs were also sought in references of all identified studies, meta-analyses and reviews. Two separate searches were conducted. The first search was undertaken prior to the previously published systematic review[5] from the inception of abstracting services to the end of 1999. This search yielded 3715 abstracts of which 123 papers were read in full for a final set of 18 RCTs. The second search focused on an update, overlapping by one year from 1999 to August 2008. This search yielded 1319 abstracts, of which 46 papers were read in full for a final set of 17 RCTs. Because the present meta-analysis focuses on outcomes that had not been extracted from the previous trials, we combined the two searches. We chose to continue to focus exclusively on RCTs instead of a more exhaustive systematic review including non-randomized controlled trials in order to make direct comparisons to the previously published systematic review[5] and to allow for combining the searches. In this way, we are able to make conclusions about progress in RCTs of psychological therapies for children with chronic pain over the past 10 years.

The central search strategy included key words to define pain and pain conditions, specific psychological interventions, and the child and adolescent population. Pain and pain condition terms included pain, chronic pain, headache disorders, abdominal, stomach ache, back, fibromyalgia, toothache, etc. Search terms for interventions included psychology, psychotherapy, behavior therapy, cognitive behavioral therapy, biofeedback, relaxation, hypnosis, imagery, family therapy, computer, and internet intervention. Search terms used for the population included child, adolescent, youth, juvenile, and pediatric. We also used terms to filter for randomized controlled trials including randomized controlled trial, randomized, controlled clinical trial, placebo, and trial. All terms were expanded in specific databases. The complete strategy is available on request from the author.

2.2. Inclusion and exclusion criteria

Trials were included in the current review if they were available as a published report of a RCT comparing a psychological treatment with primary psychotherapeutic content with placebo, other active treatment, treatment as usual, or wait-list control. The target population was children and adolescents (<19 years of age) with persistent, recurrent, or episodic pain in any body site, not associated with cancer or other life threatening malignant disease. In addition, studies had to be published (or electronically pre-published) in English, and have ten or more participants in each treatment arm at immediate post-treatment assessment. Last, studies needed to include data suitable for computation of effect sizes on at least one of the three outcomes (pain, disability, or emotional functioning).

2.3. Data extraction

Each paper was read in full in order to extract and record data on a standardized data extraction form. This form included the following information: authors and year of the published report, methods (e.g., number of treatment arms, assessment time points), participant characteristics (e.g., number of participants, age, gender distribution, type of pain problem, source), intervention details (e.g., duration of treatment, type of intervention, parent involvement),

outcomes including names of all measurement instruments reported, and notes about each trial. In addition, a table was used to record raw outcome data (e.g., means, standard deviations) from each study. The most appropriate instruments for the three outcome domains: pain intensity, functional interference or disability, and emotional functioning were selected.

2.4. Measurement domains

Three outcome domains, pain intensity, functional interference or disability, and emotional functioning, were selected as dependent variables. Because multiple measurement tools were used in some trials, we selected one measure considered most appropriate for each of the three outcome domains. To guide the choice of outcome measure, we applied two rules. First, if an outcome measure was established and occurred frequently among studies it was selected over more novel instruments. Second, given a choice between single item and multi-item self report tools, multi-item tools were chosen on the basis of inferred increased reliability. These decision rules have been previously applied in a meta-analytic review of psychological treatments for adults with chronic pain[29].

Pain intensity outcomes were most commonly reported as binary count data on a clinically significant improvement in pain (50% or greater) obtained from pain diaries. Continuous pain intensity scores were also used in some trials from numerical pain rating scales and visual analogue scales. The disability outcome was assessed using measures of school absence, functional disability, headache-related disability, and physical health-related quality of life. While these measures examine different domains of functioning, each assesses children's abilities to participate in routine, daily activities. Emotional functioning was assessed by measures of depressive symptoms, internalizing symptoms, anxiety symptoms, and psychosocial health-related quality of life. The outcomes used in each trial for each domain are shown in Table 1.

2.5. Quality Ratings

All trials were rated using a scale developed specifically for assessing the quality of psychological treatments for chronic pain[43]. The Quality Rating Scale is comprised of an overall total quality score (0–35) consisting of two subscales, a Treatment Quality subscale (0–9) covering stated rationale for treatment, manualization, therapist training, and patient engagement; and a Design and Methods Quality subscale (0–26) covering inclusion/exclusion criteria, attrition, sample description, minimization of bias (randomization method, allocation bias, blinding of assessment, and equality of treatment expectations), selection of outcomes, length of follow up, analyses, and choice of control. All papers were rated by two of the review authors (TP and AL) and consensus reached after initial comparison of ratings. Interrater reliability was calculated on the overall quality score and the two subscales.

2.6. Data collection and analysis

Data were extracted and coded on details relating to the design of the study, the participants, pain condition, method of treatment, outcome measurement tools used, and outcome data for computation of effect sizes. When data were missing on primary outcomes of interest, authors were contacted via email to obtain data necessary for effect size calculations. Four authors provided additional data upon this request. Data suitable for pooling were analyzed using RevMan v5.0 (Cochrane Collaboration).

2.6. Organization of Selected Studies

Selected studies were organized along several dimensions including intervention type and pain condition. In addition, novel treatments including comparison of different exposures and

different modalities were examined separately. Table 1 presents details of the 25 studies along these dimensions.

Psychological interventions were grouped into one of three broad categories, including omnibus cognitive-behavioral therapy (CBT), relaxation-based therapy, and biofeedback. Omnibus CBT included interventions with a behavioral and cognitive component, such as family CBT, parent operant strategies, multicomponent CBT, and pain coping skills. Relaxation-based therapy included interventions that focused exclusively on progressive muscle relaxation and similar strategies such as hypnosis. Biofeedback included interventions that were focused on biofeedback training with or without relaxation training. Effects of two different exposures of the same intervention (e.g., self-guided CBT at home versus therapist-administered CBT in clinic) were examined separately. In addition, novel treatments were identified, in this case, computer-based applications, to evaluate effects separately in these studies.

Type of chronic pain condition was categorized into three groups, headache, abdominal pain, or fibromyalgia. One trial included children who had diagnoses of either headache or abdominal pain and this study was included in both categories in the subgroup analysis by pain condition [14], and the effects of inclusion of this study in each analysis were examined.

The main focus of the meta-analysis was to examine the overall effect of psychological interventions in RCTs on pain, disability, and emotional functioning outcomes, including testing for effects of intervention type and pain condition in subgroup analyses. In the overall analysis and the pain condition analysis, treatment groups were pooled. In the analysis of the effects of intervention type, in the case where studies used multiple active treatments, the following approach was used. Analysis of multiple active treatments would require a modeling of the dependency between groups to yield accurate effect sizes across the three intervention categories[11] as each effect size from the same study involves the same sample in the control group. Because necessary information was not available in the obtained studies to model such dependencies, it was not possible to include all treatment conditions in the analysis of intervention types. Thus, in the case of multiple active treatment arms, if the intervention was the same but with a different exposure (such as therapist and home administered CBT), treatment arms were pooled (n = 8 trials). In a subgroup analysis, we examine differences between therapist and self (home-based) administration of CBT; however, there were too few trials to allow for any further comparisons by treatment exposure. If the treatment arms included intervention groups that fell into two categories (such as biofeedback and relaxation therapy), the intervention that was the focus of the study or the group hypothesized to have the best outcome due to intervention was selected for the subgroup analysis (n = 2 trials). There were too few trials to allow for any direct comparison between two intervention types. Table 1 indicates those treatments within the individual studies that were omitted from the subgroup analysis of intervention type.

In the overall analysis, two assessment points were selected for analysis: post-treatment and follow-up. Post-treatment refers to the assessment point occurring soonest following treatment, and follow-up refers to the assessment point occurring at least 3 months post-treatment but not more than 12 months (the longer time point was selected if two follow-up assessments occurred during this timeframe).

2.7. Data Analysis

The primary pain outcome that was considered was binary count data on clinically significant reduction in pain (50% or greater pain reduction). These data are reported as odds ratios (OR). The number-needed-to-treat (NNT) for benefit was also computed on the clinically significant reduction in pain outcome. The NNT represents the expected number of patients who must be

treated with psychological therapy in order to expect one additional beneficial outcome compared to the expected event rates under the control conditions. When these data were not available, continuous data on mean pain intensity were used for computation of standardized mean differences (SMD). If a study had both pain outcomes available, we chose the binary count data on clinically significant reduction in pain as this was the most commonly reported metric. All disability and emotional functioning outcomes were presented in trials using continuous data, and therefore we used the SMD. The SMD is computed from the difference between the two group's means divided by their pooled standard deviation. In social science research, Cohen[2] has defined SMD effect sizes of 0.2, 0.5, and 0.8, as representing small, medium, and large effect sizes respectively. In the current review, larger effect sizes are associated with greater differences between treatment and control groups on measures of pain intensity, disability or emotional functioning. The negative direction of the effect size indicates greater improvement for the treatment group. The overall meta-analysis with pooled treatment conditions examined outcomes at two assessment points, immediately post-treatment and at 3-month or longer follow-up. However, due to limited follow-up data, the remaining subgroup analyses were performed using the immediate post-treatment assessment only.

Heterogeneity between treatment studies was examined using the I^2 statistic. The I^2 statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error. A value greater than 50% may be considered substantial heterogeneity [15]. Both fixed-effect and random-effects models were used to pool data on the outcomes, depending upon whether significant heterogeneity was detected. In cases where no substantial heterogeneity was found ($I^2 < 50\%$), a fixed-effects model was used. However, for the three continuous outcomes, mean pain intensity, emotional functioning, and disability, a random-effects model was chosen a priori. It has been recommended that random-effects models be used for continuous outcomes and when differing measurement instruments are used across trials[15]. Therefore we made an a priori decision to use this model. A random-effects model assumes measurement error beyond subject sampling error is randomly distributed and not from systematic differences among studies. When there is no heterogeneity, fixed-effects and random-effects models produce the same results. In addition to the SMD, confidence intervals and pooled odds-ratio statistics were calculated. Confidence intervals not including zero were considered statistically significant.

Studies included in the meta-analysis were also weighted according to sample size using a least-squares approach. This approach gives studies with larger numbers of participants greater weight in the meta-analysis.

3. Results

3.1. Characteristics of included studies

Twenty-five studies involving a total of 1247 participants were included. Details of these studies are summarized in Table 1. A total of 169 studies were identified by our two searches and read in full, of which 134 were excluded because they were outside the scope of this review. The remaining 35 studies were considered for this review and coded in full. The trials used in the previous systematic review and meta-analysis[5] were automatically eligible. Of the 35 trials, 10 were excluded because: they no longer met the eligibility criterion of having ten or more participants in each treatment arm at immediate post-treatment assessment [8;22;24;38; 42]; the active treatment lacked psychological content[30]; there were no outcomes within the dependent variables of interest[10]; or they had insufficient available data for computation of effect sizes[1;4].

The 25 included studies were from 6 countries. Most studies had two treatment arms (n=14), but several studies had three (n=10) and one had four arms. The mean number of participants

per treatment arm was 21. Study participants ranged in age from 9 to 17 years with a mean age of 12.63 years (*SD*=2.36) reported in *n*=21 studies. Sixty-five percent of all participants were female. Only 10 studies reported the mean duration of the pain problem, with an average duration of 3.6 years.

Participants were recruited from hospital or clinic settings (10 studies), school (five studies), or community advertisements (five studies). Nineteen interventions were conducted with youth with headache (including migraine). Of the remaining interventions, four were for children with abdominal pain, one was for fibromyalgia, and one study included children with either headache or abdominal pain.

The psychological treatments included 12 studies of omnibus CBT interventions, nine of relaxation-based therapy, and four of biofeedback. Four studies compared two different exposures, specifically self-guided home exposure versus therapist-administered clinic exposure, of the same intervention. Two studies of home-based interventions used computer applications to deliver treatment (i.e. CD-ROM, Internet). Treatments were typically of short duration and the average number of hours of treatment contact reported in 20 studies was 6.4 hours. The format and duration of these interventions differed, with treatments ranging from 1 to 12 sessions. Sessions were conducted individually (*n*=14) and in groups (*n*=8) in the included studies. In seven studies, parents were included in the intervention.

3.2. Quality Ratings of Trials

Two independent raters scored the quality of each of the RCTs. The intra-class correlation coefficient using absolute agreement for the two raters was .90 for the Total Quality score, .88 for the Treatment Quality subscale, and .84 for the Design Quality subscale. Quality scores for each trial are shown in Table 1. For the 25 included studies, the mean overall quality score was 18.76 (*SD*=4.41), the mean design quality score was 13.48 (*SD*=3.18), and the mean treatment quality score was 5.28 (*SD*=1.65). The original scale did not include published cutoff scores for levels of treatment quality, however average scores for excellent, average, and poor trials obtained in the validation sample were 22.7(1.95), 18.71(2.25), 12.10(3.17) respectively[43]. Thus, included studies would be considered average on total quality when referenced to a subset of RCTs for psychological interventions in adults.

Spearman's correlation was conducted to examine the association among year of publication and quality ratings. These correlations were significant, indicating that as year of publication increased so did total quality, trial quality, and design quality ratings of the trials (*rho*'s = .45 to .48, *p*'s < .05). Pearson's correlation was conducted to examine the association among quality ratings and trial effect sizes, specifically, odds ratios for pain reduction. Among the 18 trials included in the analysis of clinically significant pain reduction, the correlations with quality ratings were not significant (*r*'s= −.09 to −.12), indicating no relationship between effect sizes for pain reduction and quality ratings of the trials.

3.3. Meta-Analysis Results

Overall Meta-Analysis—Table 2 provides a summary of the results of the overall meta-analysis for each of the outcomes at two assessment points (post-treatment and follow-up). Odds ratios and 95% CIs are presented for the binary event data on clinically significant reduction (> 50%) in pain, and standardized mean differences (SMDs) and 95% CIs are presented for continuous outcomes. A negative direction for SMDs indicates that the treatment condition had more improvement on outcomes than control conditions.

Of the included studies, all 25 trials had outcome data on pain intensity, 6 on disability, and 6 on emotional functioning that could be used in effect size calculations and incorporated into

the meta-analytic analyses. Ten studies had available follow-up data of 3 months or more on pain reduction and are included in the overall meta-analysis with pooled treatment conditions. Because fewer than three studies presented data on disability or emotional functioning at follow-up, these effects were not estimated.

Eighteen studies were entered into the analysis of effects of treatment on clinically significant reduction in pain. I^2 analyses did not reveal heterogeneity across studies (I^2 =17%), and therefore a fixed effects model was used. Psychological therapies, considered as a group, reduced pain intensity by at least 50% in significantly more children and adolescents, as compared to control conditions at post-treatment (OR 5.92; 95% CI 4.07 to 8.61), and this effect was significant (Z=9.31, p<.0001). At 3-month follow-up, similar effects on pain reduction were found (OR 9.88; 95% CI 5.25 to 18.58, Z=7.11, p< 0.0001). The number-needed-to-treat for benefit based on these results is 2.64 (CI 2.27 to 3.21) at post-treatment and 1.99 (CI 1.66 to 2.60) at follow-up. Forest plots in Figure 1 and Figure 2 show odds ratios and CIs for individual studies at the post-treatment and follow-up assessments.

The remaining seven studies were entered into the analysis of pain reduction using continuous data on pain intensity. Psychological therapies had a small effect on reduction of mean pain intensity compared to control conditions at post-treatment (SMD −0.37, 95% CI −0.82 to 0.09), and at follow up (SMD −0.43, 95% CI −1.04 to 0.17) and these were not significant. I^2 analyses revealed substantial heterogeneity across studies (I^2 =80%). We removed each study individually from this analysis to identify potential outliers that may account for this heterogeneity. The trial by Humphreys[18] has a much larger effect size in comparison to the other trials (SMD −1.66, 95% CI −2.32 to −1.00), and when removed from the analysis drops the I^2 value to 44%.

Six studies met criteria for the calculation of effect size for disability. Psychological therapies had a small effect on disability in comparison to control conditions at post-treatment (SMD −0.24, 95% CI −0.51 to 0.03) and this was not significant. I^2 analyses did not reveal heterogeneity across studies (I^2 =0%).

Six studies were entered into the analysis of effects of treatment on emotional functioning. Psychological therapies did not improve emotional functioning in youth compared to no treatment or placebo at post-treatment (SMD −0.12, 95% CI −0.40 to 0.17). I^2 analyses did not reveal heterogeneity across studies (I^2 =0%).

Analysis by Intervention Type—Table 3 displays the results for the effects of different intervention types (CBT, Relaxation, and Biofeedback) on pain, disability, and emotional functioning at post-treatment. As shown in Table 3, all three interventions yielded positive effects on clinically significant pain reduction, with odds ratios of 4.13 (CBT), 9.93 (Relaxation), and 23.34 (Biofeedback). Disability as an outcome was only available in studies of CBT, with a small and non-significant effect (SMD = −0.24, 95% CI −0.51, 0.03). Emotional functioning was included in 5 CBT trials (SMD = −0.09, 95% CI −0.40, 0.21) and one Biofeedback trial (SMD = −0.15, 95% CI −0.91, 0.61), producing similar small and non-significant results.

Therapist vs Self-Administered Treatment: Four trials conducted with youth with headache [12;23;25;26] directly compared two exposures of psychological therapy, therapist-administered versus self-administered (home-based). There was no significant difference in the number of patients for whom pain intensity reduced by 50% or more (OR 0.97; 95% CI 0.52 to 1.79; z=.11, p=.91) suggesting equal effectiveness of therapist-administered and self-administered treatment.

Computer-based Applications: Two trials were conducted using a comparison of computer-based applications to wait-list control conditions[3;14]. Odds ratio for clinically significant reduction in pain (OR 7.99; 95% CI 2.65 to 24.08; *z*=.3.69, *p*=.0002) is comparable to trials using other treatment formats to deliver psychological therapy.

Analysis by Pain Condition—Table 4 displays the results for the effects of psychological therapy for children presenting with different pain conditions (Headache, Abdominal pain, and Fibromyalgia) on their pain, disability, and emotional functioning at post-treatment. Clinically significant pain reduction data were available for Headache and Abdominal pain conditions, and similar, significant effects for pain reduction were found in both groups, with odds ratios of 6.10 (Headache) and 7.52 (Abdominal pain). Because the trial by Hicks and colleagues [14] included children with either abdominal pain or headache, we examined the difference in effects when this study was excluded from either the headache or abdominal pain analysis. For clinically significant reduction in pain, the analyses were not different. However, for the analysis of disability, the effect size increased and became significant when the Hicks study was removed from the analysis (SMD=−0.43, 95%CI −0.86, −0.00, z=1.96, p=.05) for the abdominal pain condition (no difference in effects was found for the headache condition analysis). Emotional functioning was unchanged in trials of children with headache, abdominal pain, or fibromyalgia, with similar small and non-significant effects. There was no difference in effects when the Hicks study was excluded from either the headache or abdominal pain condition analysis.

4. Discussion

Psychological treatments can significantly reduce pain intensity reported by children and adolescents with headache, abdominal pain, and fibromyalgia. These findings emerge from RCTs primarily comparing psychological treatments to no-treatment control conditions. Our findings were similar to previous reviews by Eccleston et al.[5] and Trautmann et al. [40] who also found that psychological interventions in RCT designs are effective in reducing pain intensity in children with headache. Importantly, however, this study extends the findings to effects of psychological treatment of children with non-headache conditions, specifically abdominal pain and fibromyalgia.

A primary goal of the meta-analysis was also to examine the efficacy of psychological treatments for reducing disability related to pain and improving emotional functioning, outcomes not previously examined in meta-analytic reviews of RCTs for children with chronic pain. The effect size calculations for disability and emotional functioning outcomes revealed small and non-significant effects of psychological treatments. The minimal impact of psychological treatment on children's pain related disability and emotional functioning may be explained by several factors including the small number of studies included in the current review, differing measures used across the included studies, and limitations of available measures.

Another contribution of this meta-analysis is that we were able to include subgroup analyses of intervention type and pain condition. These analyses demonstrated that across interventions (CBT, relaxation, and biofeedback) positive effects on pain reduction were found. Too few studies directly compared CBT, biofeedback, and relaxation to make conclusions about the superiority of one intervention over the others. In the analysis of different exposures to psychological treatment, self-administered treatment at home performed similarly to therapist-administered treatment in clinic, suggesting equivalent positive effects on pain reduction. Novel computer-based applications also produced significant pain reduction in youth compared to control conditions, and effects were of similar magnitude in comparison to face-to-face treatment delivery. It will be important in future studies to directly compare active

treatments (e.g., CBT versus biofeedback) and delivery methods (e.g., computer-based versus face-to-face).

In the subgroup analysis by pain condition, similar positive effects of pain reduction were found in children with abdominal pain and headache. However, interventions delivered to children with abdominal pain produced greater changes in disability outcomes compared to interventions delivered to children with headache or fibromyalgia. Due to the limited number of studies, it was not possible to examine systematic differences that may explain why children with abdominal pain had greater reductions in disability in these trials. Differences in intervention content, treatment exposure, therapist training, or individual characteristics of these children may be responsible for these effects.

Taken together, our findings lend support for the flexibility and utility of psychological treatments for managing chronic pain in youth. In particular, they appear to produce positive effects on pain reduction when delivered in different ways, using different cognitive and behavioral strategies, and with children with various pain conditions.

Our review also demonstrates progress in RCT trial quality and quality reporting over the past 10 years. Analyses indicated that as year of publication increased so did total quality, trial quality, and design quality ratings. Quality ratings were not, however, associated with trial outcomes. Likely, this improvement in quality reflects changes in standards for quality reporting after the publication of the CONSORT statement[28] along with increased awareness and attention to these standards by authors, reviewers, and journal editors. Nonetheless, several aspects of trial design are worth highlighting as they represent areas where design quality could be enhanced. Most of the included RCTs used treatment as usual or wait-list control conditions, making it difficult to separate treatment from placebo effects. Therefore the comparator in most trials was no treatment. Use of attention control comparison conditions would significantly enhance the quality of trial design. In addition, very limited information was available on extended follow-up to allow for testing of the maintenance of treatment effects. Previous recommendations have been made to conduct follow-up assessments for pain intervention studies at a minimum of six months following the completion of treatment and few studies in the current review provided these data. Intent-to-treat analyses and study flow (e.g., drop outs) were additional areas that were reported inconsistently in these trials.

There are several limitations of this meta-analysis that should be considered in interpreting the findings. First, our review is limited to studies that attempt to control for bias by the use of randomized controlled trial designs and does not include uncontrolled trials, case studies, or observations. The focus on RCTs alone allowed us to increase the precision of our effect size estimates. However, the ecological validity of the findings in terms of their relevance to everyday clinical practice remains to be investigated. Second, although progress has been made in applying interventions in youth with pain conditions other than headache in contrast to Eccleston et al.'s[5] systematic review and meta-analysis, additional studies with samples of children with a variety of other pain conditions are clearly needed. Third, our ability to summarize data for the meta-analysis along disability and emotional functioning outcomes was extremely limited due to the small number of studies incorporating these measurements. Fourth, there was substantial variability in measurements, particularly for disability and emotional functioning outcomes, which may have influenced effect size estimates. Given recent recommendations for specific outcome domains (PedIMMPACT) [27], and suggestions for measurement instruments, future trials are likely to have greater consistency in using well-validated outcome measures.

This study highlights several gaps in the scientific study of psychological interventions to reduce chronic pain and improve functional outcomes in a pediatric population that are

important areas for future research. First, the sample size of many of the included studies was quite small with an average treatment arm of 21 subjects. Multi-site recruitment will be necessary to produce large enough sample sizes that allow for stronger tests of treatment efficacy and for examination of individual differences in treatment response. Second, virtually no information is available on child individual differences such as age, gender, or pain duration that may influence treatment response. Third, the evidence base contains studies with participants recruited from various sites, including patients attending clinics, people attending schools, and those responding to advertisement. Future comparisons between recruitment sites and between clinic attendees and non-clinic attendees will be instructive. Fourth, social desirability effects were largely uncontrolled in these studies. Given the absence of attention control comparisons it is possible that treatment effects are due to a host of patient-therapist factors non-specific to treatment. Finally, improvements in measurement technology and practice are necessary. Measurement over a broader array of outcome domains is necessary [27]. However, further use and validation of existing measures would be helpful.

In particular, it will be important to establish additional validation of commonly used measures of children's functioning to address the significant gaps in knowledge of how these measures perform[32]. For example, there are no established cut-off scores on most disability measures, and therefore interpretation of the clinical relevance of scores is not possible. Moreover, although the domain of functioning is by definition multi-dimensional, factor analyses have not been performed on most available measures of disability[33], limiting sensitivity in detecting changes in specific areas of functioning. While treatment goals for the child with chronic pain often center around accomplishing improvement in the child's ability to participate in activities of daily living including school attendance and taking part in social or physical activities, further research will be necessary to ensure that such changes in function can be adequately measured[34].

In conclusion, although findings from this meta-analysis are promising, suggesting that psychological treatments produce a substantial improvement in children's pain intensity across several chronic pain conditions, there remain important challenges to address in future work. Although the evaluation of specific treatment components is beyond the scope of this review, it is important to consider how psychological therapies developed for children and adolescents with chronic pain address core mechanisms expected to lead to functional improvements. Such consideration may lead to further treatment development, enhancing current behavioral and cognitive-behavioral treatments to address mechanisms of change. Although research has highlighted the lack of direct correspondence between children's pain intensity and level of disability[31], most psychological interventions for pediatric pain were developed for the stated goal of reducing pain. Theory of how psychological intervention strategies lead to change in physical and emotional functioning related to children's pain is needed. Last, as we move into an era where technology is being used increasingly in the delivery of healthcare, including to children with chronic pain[3;14;35], a challenge will be to identify the most relevant and effective components of psychological interventions, and to consider how they can be adapted for delivery via technological media.

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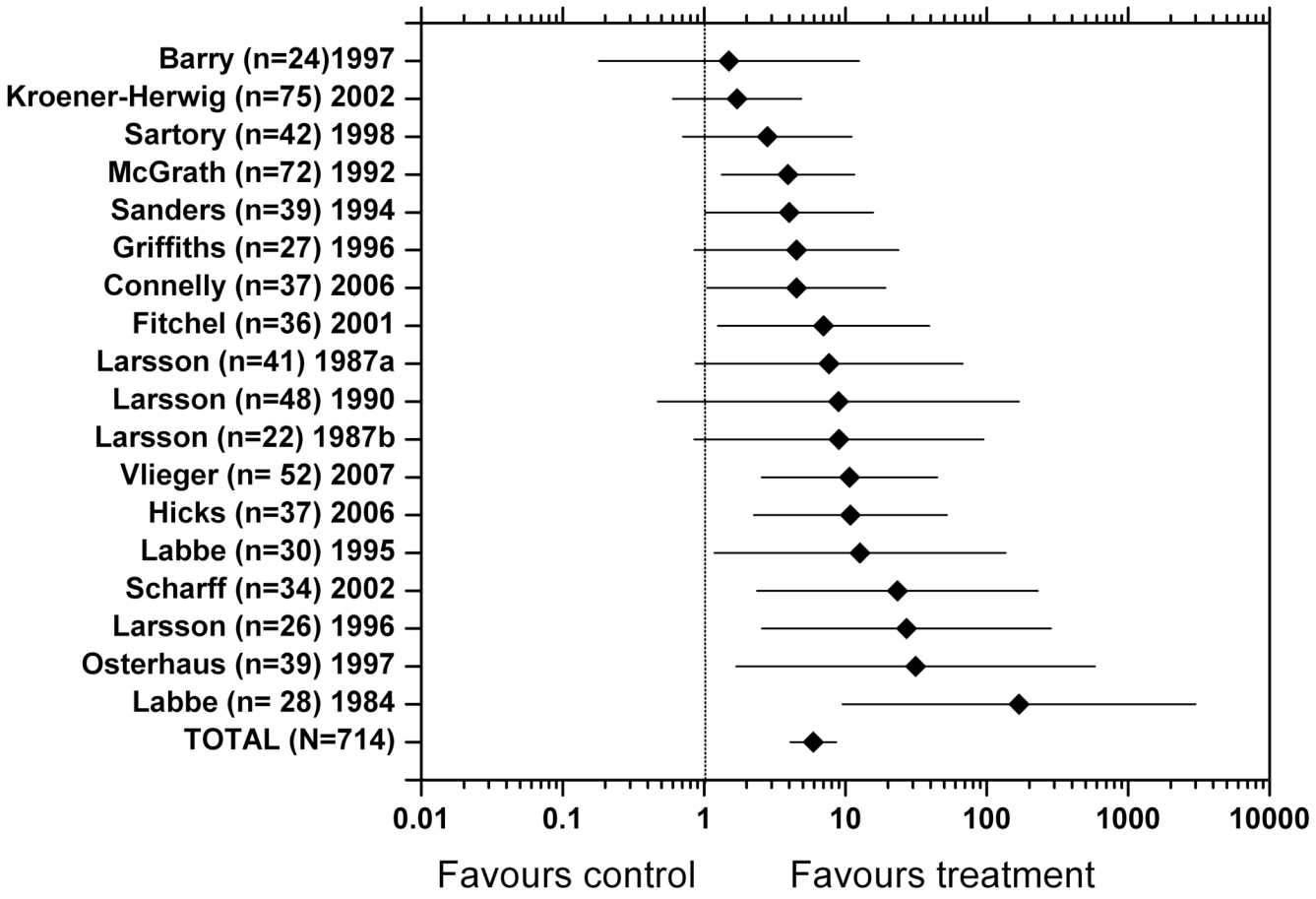

Figure 1.
Clinically significant reduction in pain at post-treatment by study and overall.

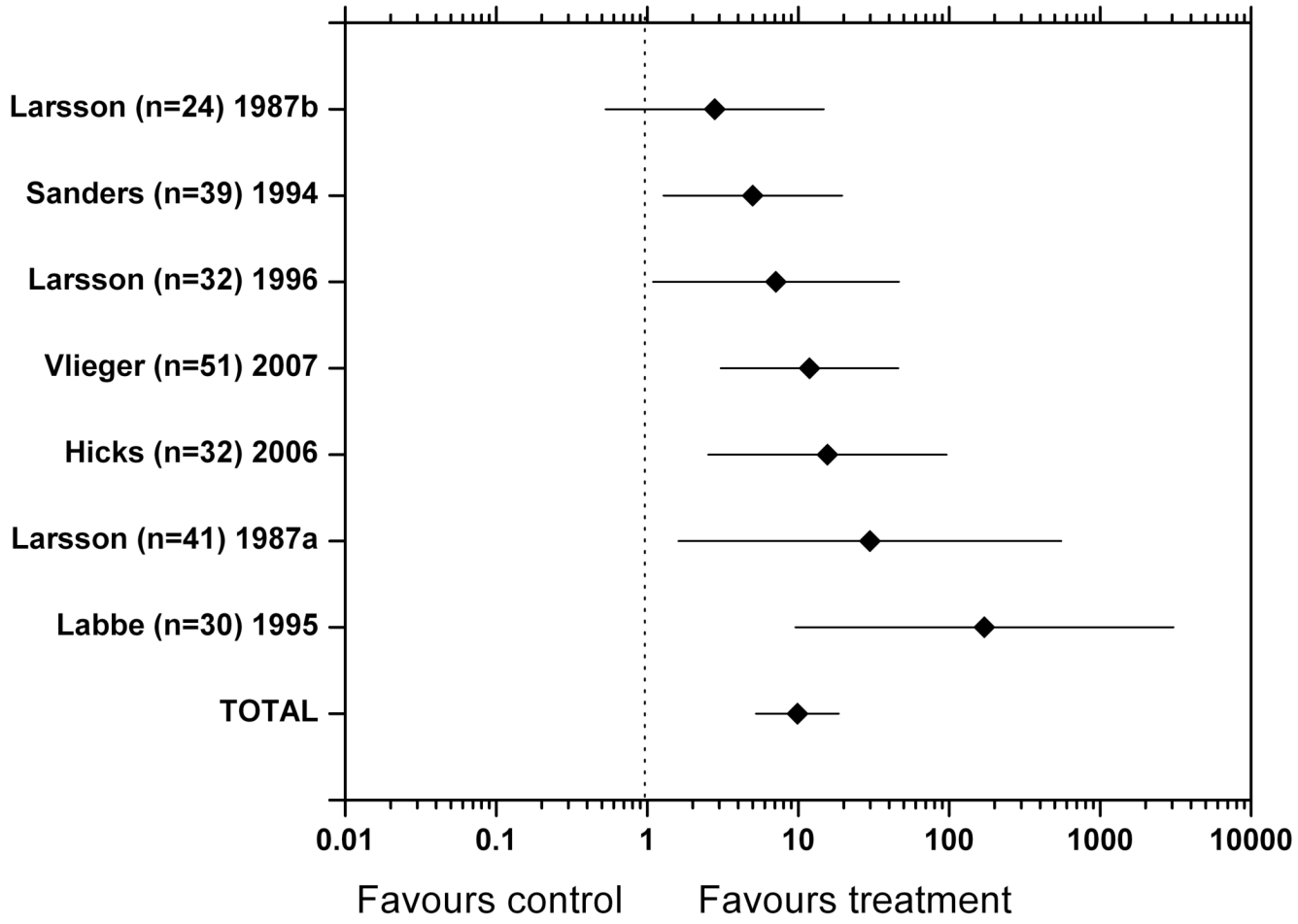

Figure 2.
Clinically significant reduction in pain at follow-up by study and overall.

Table 1

Characteristics of included RCTs.

Authors (year)	Pain Condition	Sample Description (M age, range, % female)	Intervention Type (Group n's)	Treatment Exposure	Pain Intensity Outcome	Emotional Functioning Outcome	Physical Functioning Outcome	Quality Ratings
Barry & von Baeyer (1997)	Headache	9.4, 7–12 years; 66% female	Brief CBT group treatment (n=12); wait list control (n=17)	Two 90 min sessions	Headache diary using 0–10 NRS intensity	Diary – Mood rating	Diary- School absences	TQ=3 DQ=11 Total=14
Bussone et al. (1998)	Headache	11.1/13.0; 11–15 years, 50% female	Biofeedback-assisted relaxation (n=20); Relaxation placebo control (n=10)	10 sessions, 40 minutes each	Headache diary using 0–4 intensity	State Trait Anxiety Inventory for Children	None	TQ=5 DQ=13 Total=18
Connelly et al. (2006)	Headache	10.0, 7–12 years, 49% female	CBT delivered via CD-ROM (n=14); Wait-list control (n=17)	4 one-hour modules	Headache diary	None	Pediatric Migraine Disability Assessment	TQ=8 DQ=16 Total=24
Fichtel & Larsson (2001)	Headache	15.4; 13–18 years 69.4% female	Relaxation training (n=20); Wait-list control (n=16)	8–10 sessions, 45 minute duration	Headache diary using 0–5 intensity	None	None	TQ=4 DQ=11 Total=15
Griffiths and Martin (1996)	Headache	11.4/11.5/11.1; 10–12 years; 50% female	Clinic based CBT (n=17); Home based CBT (n=17); Wait-list control (n=17)	8 sessions, 90 minutes; Home based treatment: 3 sessions + written manual for home over 9 weeks	Headache diary using 0–5 intensity	Children's Manifest Anxiety Scale, Children's Depression Scale[b]	None	TQ=5 DQ=13 Total=18
Hicks et al. (2006)	Headache, abdominal pain	11.7, 9–17 years; 64% female	Online CBT (n=21); Standard medical care waitlist control (n=16)	7 online chapters (1/week)	Pain diary using 0–10 NRS intensity	Pediatric Quality of Life Inventory (Psychosocial Health Summary)	Pediatric Quality of Life Inventory (Physical Health Summary)	TQ=8 DQ=19 Total=27
Humphreys et al. (2000)	Abdominal pain	9.75; 4–18 years; 59% female	Fiber + Biofeedback (n=15)*, Fiber + Biofeedback + CBT (n=16)*, Fiber + Biofeedback + CBT + Parent Training (n=15) Fiber only Control Group (n=15)	8 sessions	Pain diary using visual analogue scale	None	School absences	TQ=5 DQ=9 Total=14
Kashikar-Zuck et al. (2005)	Juvenile Fibromyalgia	15.8; 13–17 years, 100% female	CBT coping skills training (n=13); Self-monitoring (n=14)	6 sessions, 2 telephone check-ins (1/week)	Visual analogue scale	Children's Depression Inventory	Functional Disability Inventory	TQ=7 DQ=18 Total=25

Authors (year)	Pain Condition	Sample Description (M age, range, % female)	Intervention Type (Group n's)	Treatment Exposure	Pain Intensity Outcome	Emotional Functioning Outcome	Physical Functioning Outcome	Quality Ratings
Kroner-Herwig & Denecke (2002)	Headache	12.1; 10–14 years; 53.3% female	Therapist group administered CBT (n=29); Self-help CBT (n=27), Wait-list control (19)	8 sessions, 90 minutes duration	Headache diary	None	None	TQ=7 DQ=12 Total=19
Labbe (1995)	Headache	12; 8–18 years; 43.3% female	Relaxation training only (n=10)*; biofeedback + relaxation training (n=10) ; Waitlist control (n=10)	10 sessions, 45 minutes each over 7 weeks	Headache index	None	None	TQ=2 DQ=9 Total=11
Labbe & Williamson (1984)	Headache	10.8;7–16 years; 50% female	Biofeedback + relaxation training (n=14); Waitlist control (n=14)	10 sessions, 40 minutes each over 7 weeks	Headache diary using 0–5 intensity	None	None	TQ=4 DQ=12 Total=16
Larsson & Carlsson (1996)	Headache	Mean not reported; 10–15 years; 96.2% female	Group relaxation training (n=13); Control (n=13)	10 sessions, 20 minute duration for 5 weeks	Headache diary using 0–5 intensity	None	None	TQ=6 DQ=14 Total=20
Larsson et al. (1987a)	Headache	Mean not reported; 16–18 years; 86.9% female	Self-help relaxation (n=16); Therapist assisted relaxation (n=14); Self monitoring control (n=11)	9 sessions, 45 minute duration for 5 weeks = 6 hours therapist assisted group; 2 hours self-help group	Headache diary	None	None	TQ=6 DQ=15 Total=21
Larsson et al. (1987b)	Headache	Mean not reported; 16–18 years; 94,4% female	Self-help relaxation (n=12); Problem-discussion (n=10); Self-monitoring control (n=12)	Self help: 4 audiotapes (10–15 min), 3 hours of therapist time. Problem discussion: 7 hours of therapist time	Headache diary using 0–5 intensity	None	None	TQ=5 DQ=11 Total=16
Larsson, Melin, & Doberl (1990)	Headache	16–18 years; 89.8% female	Self-help relaxation training (n=31); Waitlist control (n=17)	5 audiotapes used over 5 weeks	Headache diary using 0–5 intensity	Beck Depression Inventory[c], Children's Manifest Anxiety Scale[c]	None	TQ=4 DQ=8 Total=12
McGrath et al. (1988)	Headache	13.1;9–17 years; 69.7% female	Relaxation training (n=32); Attention placebo control (n=37);Own best efforts control (n=30)	6 1-hour/week sessions	Headache diary	None	None	TQ=7 DQ=16 Total=23

Authors (year)	Pain Condition	Sample Description (M age, range, % female)	Intervention Type (Group n's)	Treatment Exposure	Pain Intensity Outcome	Emotional Functioning Outcome	Physical Functioning Outcome	Quality Ratings
McGrath et al. (1992)	Headache	Mean age not reported; 11–18 years; 72.4% female	Self administered CBT (n=24), Therapist administered CBT (n=23), Attention control (n=26)	8 weekly sessions (60 minutes each in clinic group)	Headache diary using 0–5 intensity	Poznanski Depression Scale[c]	None	TQ=2 DQ=13 Total=15
Osterhaus et al. (1997)	Headache	15.2;12–22 years; 74.4% female	Multicomponent CBT with biofeedback (n=25), Waitlist control (n=14)	8 sessions, 4-group 90 minutes and 4-individual 50 min each	Headache diary using 5 point intensity scale			TQ=6 DQ=12 Total=18
Passchier et al. (1990)	Headache	13.5 relaxation training group, 13.7 placebo; range not reported; 49.0% female	Relaxation training (n=110), Placebo control (n=92)	10 sessions; 10–20 minute each	Headache diary using 0–5 intensity	None	None	TQ=5 DQ=10 Total=15
Richter et al. (1986)	Headache	12.9; 9–18 years; 66.7% female	Relaxation training (n=15), Cognitive coping (n=15), Attention control (n=12)	6 sessions, 60 minutes each	Headache diary	None	None	TQ=6 DQ=14 Total=20
Robins et al. (2005)	Abdominal pain	11.3; 6–16 years; 56.5% female	CBT family intervention (n=40); Standard medical care (n=29)	5 sessions, 40 minute duration	Abdominal Pain Index, 0–10 NRS	None	Functional Disability Inventory	TQ=7 DQ=20 Total=27
Sanders et al. (1994)	Abdominal pain	8.9; 7–14 years, 63.6% female	CBT family intervention (n=22); Standard pediatric care (n=22)	Six 50 minute sessions	Pain diary (0–10 VAS intensity)	Child Behavior Checklist (Internalizing subscale)	None	TQ=4 DQ=15 Total=19
Sartory et al. (1998)	Headache	11.3; 8–16 years; 39.5% female	Biofeedback + CBT coping skills (n=15), Relaxation + CBT coping skills (n=15), Pharmacologic treatment (Metropolol) control (n=13)	10 sessions, 60 minutes each	Headache diary using 1–10 intensity	None	None	TQ=6 DQ=13 Total=19
Scharff et al. (2002)	Headache	12.8; 7–17 years; 66.7% female	Biofeedback + cognitive skills in stress management (n=13); Biofeedback placebo (n=11), Wait-list control (n=12)	4 one-hour sessions	Headache diary using 0–4 scale (highest intensity)	None	None	TQ=4 DQ=15 Total=19

Authors (year)	Pain Condition	Sample Description (M age, range, % female)	Intervention Type (Group n's)	Treatment Exposure	Pain Intensity Outcome	Emotional Functioning Outcome	Physical Functioning Outcome	Quality Ratings
Vlieger et al. (2007)	Abdominal pain and IBS	13.2; 8–18 years; 67% female	Hypnotherapy (n=27); Standard medical care + attention control (n=25)	Six 50 minute sessions	Pain diary using affective faces scale (0–3 intensity)	None	None	TQ=6 DQ=18 Total=24

Notes: TQ = treatment quality, range = 0–9; DQ = design quality, range = 0–26; and Total = Total quality score, range = 0–35

[a] refers to arms that were omitted from the subgroup analysis by intervention type

[b] refers to measure selected for analysis when multiple measures in the same outcome domain were available

[c] refers to measures omitted from analyses due to insufficient data

Table 2

Summary of Meta-Analytic Findings: Pooled Treatment Conditions at Post-treatment and Follow up

Outcome	**k**	**Total N**	**OR**	**95% CI**	**Z**	**P**	**I^2**
Post-treatment: Clinically significant improvement in pain	18	714	5.92	4.07, 8.61	9.31	.0001	17%
Follow up: Clinically significant improvement in pain	7	239	9.88	5.25, 18.58	7.11	.0001	24%
Outcome	**k**	**Total N**	**SMD**	**95% CI**	**Z**	**P**	**I^2**
Post-treatment: Mean pain intensity	7	287	−0.37	−0.82, 0.09	1.59	.11	80%
Follow up: Mean pain intensity	3	137	−0.43	−1.04, 0.17	1.41	.16	62%
Post-treatment: Disability	6	220	−0.24	−0.51, 0.03	1.73	.08	0%
Post-treatment: Emotional Functioning	6	204	−0.12	−0.40, 0.17	0.80	.42	0%

Note: k = number of studies, N = number of subjects; OR = odds ratios, SMD = standardized mean difference, CI = confidence interval, I^2 = heterogeneity of studies

Table 3

Meta-Analytic Results for Intervention Type at Post-Treatment Assessment

Outcome	Intervention	k	Total N	OR	95% CI	Z	p	I^2
Clinically	CBT	9	406	4.13	2.61, 6.54	6.05	.0001	0%
significant pain	Relaxation	6	225	9.93	4.38, 22.54	5.49	.0001	0%
reduction	Biofeedback	3	82	23.34	5.87, 92.72	4.48	.0001	34%
Outcome	**Intervention**	**k**	**Total N**	**SMD**	**95% CI**	**Z**	**p**	**I^2**
Disability	CBT	6	220	−0.24	−0.51, 0.03	1.73	.08	0%
	Relaxation	0	0	-	-	-	-	-
	Biofeedback	0	0	-	-	-	-	-
Emotional	CBT	5	174	−0.09	−0.40, 0.21	0.59	.55	0%
functioning	Relaxation	0	0	-	-	-	-	-
	Biofeedback	1	30	−0.15	−0.91, 0.61	0.40	.69	n/a

Note: CBT = omnibus cognitive-behavioral therapy, k = number of studies, N = number of subjects; OR = odds ratios, SMD = standardized mean difference, CI = confidence interval, I^2 = heterogeneity of studies

Table 4

Meta-analytic Results for Type of Pain Condition at Post-Treatment Assessment

Outcome	Condition	k	Total N	OR	95% CI	Z	p	I^2
Clinically	Headache	16	632	6.10	4.06, 9.15	8.72	.0001	23%
significant	Abdominal	3	128	7.52	3.29, 17.16	4.79	.0001	0%
pain reduction	Fibromyalgia	0	0	-	-	-	-	-
Outcome	**Condition**	**k**	**Total N**	**SMD**	**95% CI**	**Z**	**p**	**I^2**
Disability	Headache	3	97	−0.08	−0.48, 0.33	0.38	.71	0%
	Abdominal	3	133	−0.33	−0.68, 0.02	1.85	.06	0%
	Fibromyalgia	1	27	−0.18	−0.93, 0.58	0.45	.65	n/a
Emotional	Headache	4	138	−0.16	−0.51, 0.19	0.88	.38	0%
functioning	Abdominal	2	76	−0.10	−0.55, 0.35	0.43	.67	0%
	Fibromyalgia	1	27	.07	−0.68, 0.83	0.18	.18	n/a

Note: k = number of studies, N = number of subjects; OR = odds ratios, SMD = standardized mean difference, CI = confidence interval, I^2 = heterogeneity of studies