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Psychological therapies for the management of chronic and recurrent pain in children and adolescents

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Abstract

Background—Chronic pain affects many children, who report severe pain, distressed mood, and disability. Psychological therapies are emerging as effective interventions to treat children with chronic or recurrent pain. This update adds recently published randomised controlled trials (RCTs) to the review published in 2009.

Objectives—To assess the effectiveness of psychological therapies, principally cognitive behavioural therapy and behavioural therapy, for reducing pain, disability, and improving mood in children and adolescents with recurrent, episodic, or persistent pain. We also assessed the risk of bias and methodological quality of the included studies.

Search methods—Searches were undertaken of MEDLINE, EMBASE, and PsycLIT. We searched for RCTs in references of all identified studies, meta-analyses and reviews. Date of most recent search: March 2012.

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CONTRIBUTIONS OF AUTHORS

Christopher Eccleston oversaw the project and contributed to the design, analysis and authoring of the text and is responsible for any future update of this review.

Amy Lewandowski, Emma Fisher, Emily Law, Stephen Morley, Tonya Palermo, and Amanda Williams, all contributed to the design, analysis and authoring of the text.

DECLARATIONS OF INTEREST

None known.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. In Eccleston 2009 CENTRAL database was searched to recruit studies. In this review we judged this to have a low yield and any potential studies could be identified through PsychINFO, EMBASE, and MEDLINE.
2. In this update of the review, there is more clarity around how treatment and control groups were combined.
3. In Eccleston 2009 Odds Ratios and Risk Ratios were reported for dichotomous outcomes. In this review we only report Risk Ratios.

Selection criteria—RCTs with at least 10 participants in each arm post-treatment comparing psychological therapies with active treatment were eligible for inclusion (waiting list or standard medical care) for children or adolescents with episodic, recurrent or persistent pain.

Data collection and analysis—All included studies were analysed and the quality of the studies recorded. All treatments were combined into one class: psychological treatments; headache and non-headache outcomes were separately analysed on three outcomes: pain, disability, and mood. Data were extracted at two time points; post-treatment (immediately or the earliest data available following end of treatment) and at follow-up (at least three months after the post-treatment assessment point, but not more than 12 months).

Main results—Eight studies were added in this update of the review, giving a total of 37 studies. The total number of participants completing treatments was 1938. Twenty-one studies addressed treatments for headache (including migraine); seven for abdominal pain; four included mixed pain conditions including headache pain, two for fibromyalgia, two for pain associated with sickle cell disease, and one for juvenile idiopathic arthritis. Analyses revealed five significant effects. Pain was found to improve for headache and non-headache groups at post-treatment, and for the headache group at follow-up. Mood significantly improved for the headache group at follow-up, although, this should be interpreted with caution as there were only two small studies entered into the analysis. Finally, disability significantly improved in the non-headache group at post-treatment. There were no other significant effects.

Authors' conclusions—Psychological treatments are effective in reducing pain intensity for children and adolescents (<18 years) with headache and benefits from therapy appear to be maintained. Psychological treatments also improve pain and disability for children with non-headache pain. There is limited evidence available to estimate the effects of psychological therapies on mood for children and adolescents with headache and non-headache pain. There is also limited evidence to estimate the effects on disability in children with headache. These conclusions replicate and add to those of the previous review which found psychological therapies were effective in reducing pain intensity for children with headache and non-headache pain conditions, and these effects were maintained at follow-up.

Medical Subject Headings (MeSH)

*Pain Management; Abdominal Pain [therapy]; Chronic Disease; Cognitive Therapy; Fibromyalgia [therapy]; Headache [therapy]; Hemoglobin SC Disease [complications]; Mood Disorders [therapy]; Pain [psychology]; Psychotherapy [*methods]; Randomized Controlled Trials as Topic; Recurrence

MeSH check words

Adolescent; Child; Humans

PLAIN LANGUAGE SUMMARY

Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Psychological therapies (relaxation, hypnosis, coping skills training, biofeedback, cognitive behavioural therapy) are treatments that may help people manage pain and its disabling consequences. For children and adolescents there is good evidence that both relaxation and cognitive behavioural therapy (treatment that helps people test and revise their thoughts and actions) are effective in reducing the severity and frequency of pain in chronic headache, recurrent abdominal pain, fibromyalgia, sickle cell disease, and juvenile idiopathic arthritis immediately after treatment is delivered. Psychological therapies also have a lasting effect

for improving mood and reducing pain for chronic headache. Forty-nine per cent of children who received psychological therapies reported less pain compared with 17% of children who did not receive a psychological therapy. Disability is improved immediately after treatment for many pain conditions (not chronic headache) which helps young people to participate in important daily activities. More studies are needed to understand whether psychological therapies can improve mood and have more lasting effects on pain and disability in other groups of young people who have chronic pain.

BACKGROUND

Description of the condition

This review is an update of a previously published review in The Cochrane Database of Systematic Reviews (Eccleston 2009) on 'Psychological therapies for the management of chronic and recurrent pain in children and adolescents'. Chronic and recurrent pain (pain lasting more than three months) is a common problem in young people. Recent epidemiology gives the prevalence at 15% to 30%, with 8% of children described as having severe and frequent pain (Perquin 2000; Perquin 2001; Stanford 2008). The most common location for pain is in the head, abdomen, and limbs (Perquin 2000). All types of chronic and recurrent pain are more commonly reported by girls, and peak in incidence at ages 14 to 15 years (Stanford 2008). Young people report pain to be distressing and interfering, and in some cases this can be severely debilitating, affecting all aspects of a child's life (Bursch 1998; Palermo 2000) and the lives of their parents and family members (Walker 1989; Palermo 2005). The deleterious effects of untreated pain in childhood can also extend to adulthood (Fearon 2001).

Description of the intervention

There is a broad family of treatments included in the general term "psychological". In essence, treatments have been developed that are specifically designed to alter psychological processes thought to underlie or significantly contribute to pain, distress, and/or disability. The design of psychological treatments is normally informed by specific theories of the etiology of human behaviour, or have developed pragmatically through observation and study of response to intervention. Behavioural and cognitive treatments designed to ameliorate pain, distress and disability were first introduced with adults over 40 years ago and have become well established (Fordyce 1968; Keefe 2004). A companion review of psychological treatments for the management of chronic pain in adults is also published (Eccleston 2009a).

How the intervention might work

In paediatric practice, however, the treatments have a shorter history and different therapeutic aims and components than those used with adults. In general, psychological treatments have aimed to control pain and modify situational, emotional, familial, and behavioural factors that play a role in pain or related consequences (e.g., McGrath 1990). A variety of intervention strategies have been designed to reduce pain sensations, increase comfort, and/or reduce associated disability and dysfunction in children with pain conditions. Behavioural strategies include relaxation training, biofeedback, and behavioural management programs (e.g., teaching parents operant strategies to reinforce adaptive behaviours such as school attendance). Cognitive strategies include hypnosis, stress management, guided imagery, and cognitive coping skills (Palermo 2012).

Cognitive behavioural programs incorporate elements of both behavioural and cognitive strategies. Given that headache and abdominal pain are the most common types of recurrent pain in children, most of the treatment literature has focused on these two populations. By

far the most commonly described treatment is relaxation training and/or biofeedback for headache, and recommendations have been made to offer psychological treatment as a matter of routine care for children with headaches (Masek 1999). In an effort to enhance the efficiency of psychological treatments for children with headache, more recent treatment developments have compared different elements of relaxation training and biofeedback with a variation in treatment formats (individual and group), treatment dose, and treatment setting (clinic, school, and home).

Psychological therapies have also been developed to treat children with non-headache chronic and recurrent pain including children with abdominal, musculoskeletal, and disease-related pain. Multidisciplinary pain treatment programs for children have recently become a standard of care (McGrath 1999a), and now many specialised pain clinics are available for children with chronic or recurrent pain, which may involve outpatient care or intensive inpatient rehabilitation. Such programs offer physical rehabilitation, psychological treatment, and medical strategies, and aim to restore function rather than provide pain relief. There is evidence from case series and uncontrolled studies for the effectiveness of multidisciplinary treatment with psychological therapy for paediatric chronic and recurrent pain (Eccleston 2003b).

Why it is important to do this review

Several reviews have documented the effectiveness of psychological therapies for children with headache, abdominal, and disease-related pain (Janicke 1999; Kibby 1998; Holden 1999; Huertas-Ceballos 2008; Walco 1999; Weydert 2003). Three reviews have used data pooling techniques for studies of children with headache (Eccleston 2009; Hermann 1995; Trautmann 2006). In their review of paediatric migraine Hermann 1995 found that biofeedback and muscle relaxation are more effective than placebo treatments and prophylactic drug treatments in controlling headache. In the previous published Cochrane review (Eccleston 2009), we found that psychological treatments were effective in reducing pain intensity in youths with headache. Trautmann 2006 conducted a meta-analysis of psychological treatment for recurrent headache in children finding small effect sizes across three headache variables: frequency, duration, and intensity, although reduction in pain intensity at post-treatment was a statistically significant effect. A large binomial effect size of 50% or greater reduction in headache symptoms was reported.

The previous Cochrane review (Eccleston 2009) is now out of date (Shojania 2007). Developments in paediatric psychology have led to new populations of children being treated. The aim of this review is to further update the published evidence on the efficacy of psychological treatments for chronic and recurrent pain in children and adolescents in outcomes with chronic, non-headache, pain.

OBJECTIVES

- The primary objective of this update review was to determine the effectiveness of psychological therapy for chronic and recurrent pain in children and adolescents compared with other psychological therapies, active treatment, waiting list, or medical care on clinical outcomes of pain severity, mood, and disability.
- The secondary objective was to describe the methodological quality of the studies.

METHODS

Criteria for considering studies for this review

Types of studies—Randomised controlled trials (RCTs) comparing a credible psychological treatment, or a compound treatment with credible primary psychological content, active treatment, treatment as usual, or waiting list control, in paediatric chronic or recurrent pain. Content was judged credible if it referred to a scientific theory of psychological action. Studies were excluded if the pain was associated with a malignant life-threatening disease.

Studies were included if they:

- were available as a full publication or report of a RCT;
- had a design that placed a psychological treatment as an active treatment of primary interest;
- had a psychological treatment with definable psychotherapeutic content (although not necessarily delivered by someone with psychological qualifications);
- were published (or electronically pre-published) in a peer-reviewed scientific journal;
- were with participants reporting chronic (i.e., three months duration of pain) or recurrent (i.e., episodic) pain; and
- had 10 or more participants in each treatment arm at the end-of-treatment assessment.

Types of participants—Children and adolescents (<18 years) reporting persistent, recurrent or episodic pain in any body site, not associated with cancer or similar life threatening malignant disease.

Types of interventions—Studies were included if at least one trial arm consisted of a psychological intervention, and a comparator arm used, active treatment, treatment as usual, or waiting list control.

Types of outcome measures—

- Data were collected on descriptive characteristics of patients and characteristics of the treatments, including treatment setting and amount of treatment time.
- All measurement instruments reported in each study were assessed and recorded. The most appropriate measurement instruments for the three domains of pain, (physical) disability, and mood were selected.
- Any mention of adverse events was also recorded.

Search methods for identification of studies

Electronic searches—Randomised controlled trials (RCTs) of any psychological therapy for paediatric chronic or recurrent pain were identified by searching MEDLINE, EMBASE and PsycINFO from their inception to March 2012. The Cochrane Central Register of Controlled Trials (CENTRAL) was searched in the previous versions of this review (Eccleston 2003a; Eccleston 2009). However, for this update of the review it was agreed by all authors that the sensitivity of CENTRAL for pain trials was low and that all updated trials could be identified through the alternative databases and by contacting study authors

for further trials. Three separate searches have been undertaken. The first search was undertaken from inception of the abstracting services to the end of 1999 (Eccleston 2003a), the second searched databases from 1999 to 2008 (Eccleston 2009), and the third searched databases from 2008 to March 2012.

Data collection and analysis

Selection of studies—The selection of included studies was made using the following criteria; the study had to be RCT in design and published in a peer-reviewed journal, include children (<18 years of age) who have chronic pain (non-malignant), include a psychological intervention as an active treatment, and have > 10 participants in each arm at post-treatment. Psychological interventions were considered for inclusion if they had credible, recognisable psychological/psychotherapeutic content and were specifically designed to change the child's behaviour, cognition, and/or outcomes. There were no additional criteria (regarding sample size or other) added for the purposes of this update, therefore, the trials used in the previous systematic review and meta-analysis (Eccleston 2009) were considered automatically eligible and included.

Data extraction and management—Data were extracted on details relating to the design of the study, the participants, primary diagnosis, method of treatment, outcome measurement tools used, and outcome data for computation of effect sizes. When data were missing on primary outcomes of interest, we contacted trial authors via email to obtain data necessary for effect size calculations. Data suitable for pooling were entered into RevMan 5.1.

Assessment of risk of bias in included studies—The risk of bias was measured using the recommended Cochrane 'Risk of bias' tool (Higgins 2011). We selected five categories from this tool; random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), and selective reporting (reporting bias). Two categories were excluded for the purposes of this review as they were deemed redundant because of the nature of delivering or receiving a psychological intervention. The categories were 'blinding (performance bias and detection bias)' and 'blinding participants and personnel'. Judgements were made on the categories using the following rules. Random sequence generation judgements were based on whether authors gave a convincing method of randomisation. Allocation concealment bias judgements were based on whether there were convincing methods used for random allocation to take place. Participants being stratified by age or gender were not deemed as biased. Blinding of outcome assessment was judged on whether the measures were taken by a third party who was blind to the treatment condition. Incomplete outcome data bias judgements were based on whether attrition was fully reported. Authors had to report attrition at each measurement time point (post-treatment and follow-up), and state whether there were any significant differences between completers and non-completers. Finally, selective reporting bias was judged on whether data could be fully extracted for analyses in this review. If authors provided data when requested, this category would be marked as 'low bias'.

Assessment of quality of included studies—A quality rating scale designed specifically for studies of psychological treatments in chronic pain was applied (Yates 2005). All papers were scored by two of the review authors and consensus reached after initial comparison of ratings. Interrater reliability was calculated. The quality rating scale provides an overall total quality score (zero to 35) consisting of two subscales: a treatment quality scale (zero to nine) covering stated rationale for treatment, manualisation, therapist training, and patient engagement; and a design and methods scale (zero to 26) covering

inclusion/exclusion criteria, attrition, sample description, minimisation of bias (randomisation method, allocation bias, blinding of assessment, and equality of treatment expectations), selection of outcomes, length of follow-up, analyses, and choice of control. This comprehensive quality assessment method was used in place of the single item of allocation bias.

Measures of treatment effect—All treatments labelled as psychological were combined in the following meta-analyses, and designated “Treatment”. Similarly, all control conditions were combined and designated “Control”. Where more than one intervention or control group was reported the intervention or control arms were combined to create a single pair-wise comparison in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The studies were divided into two groups. The first group was labelled “headache” and the second group was labelled “non-headache”. Two assessment points were also selected: post-treatment and follow-up. Post-treatment is the assessment point occurring soonest following treatment (often after a delay of several weeks to allow for recording of episodic pain), and follow-up is the assessment point at least three months after the post-treatment assessment point, but not more than 12 months, and the longer time point was selected if there were two follow-up assessments within this time frame. Therefore, four separate comparisons were designed comprising two forms of comparator (Treatment, Control) and two assessment time points (post-treatment and follow-up). They were labelled as follows.

1. Treatment versus Control (headache) post-treatment.
2. Treatment versus Control (headache) follow-up.
3. Treatment versus Control (non-headache) post-treatment.
4. Treatment versus Control (non-headache) follow-up.

Multiple measurement tools were typically used in each study. For each comparison, three outcomes were identified and labelled “Pain”, “Disability”, and “Mood”. From each trial we selected the measure considered most appropriate for each of the three outcomes. 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. Studies did not necessarily report data in all three outcomes. For headache treatments, the data for pain outcomes were dichotomous so relative ratios or risk ratios (RR) were used, and we calculated numbers-needed-to-treat-to-benefit (NNTBs). For disability and mood outcomes, continuous data were used. Continuous data were used for pain, disability, and mood for non-headache studies. Effect sizes can be interpreted as follows; small = 0.2, medium = 0.5, large = 0.8 (Cohen 1992).

Data synthesis—For dichotomous outcomes, such as achieved (or failed to achieve) 50% reduction in pain, we calculated the odds ratio (OR) using 95% confidence intervals (CI) and a random-effects model. For ease of interpretation, the risk ratio (RR), and NNTB are also reported. For continuous outcomes (such as rating scales) we calculated the standardized mean differences using 95% CI and a random-effects model. The heterogeneity of the findings is also reported.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

Three separate searches have been undertaken. The first search was undertaken from inception of the abstracting services to the end of 1999 (Eccleston 2003a). This yielded 3715 abstracts, of which 123 were read in full, identifying 18 RCTs. The second search, which updated the original review, was undertaken focusing on the 10 years since the previous search, overlapping by one year; from 1999 to 2008 and was later published (Eccleston 2009). This yielded 1319 abstracts, of which 45 papers were read in full, identifying a further 16 RCTs, giving a total set of 34. However, five studies were later excluded because they did not meet the minimum criteria of 10 participants in each arm, therefore, leaving 29 studies. The third, which searched databases from 2008 to March 2012 yielded 851 abstracts, of which 25 papers were read in full, and eight further RCTs were included in the review, giving a total of 37 RCTs (Abram 2007; Alfven 2007; Barakat 2010; Barry 1997; Bussone 1998; Connelly 2006; Duarte 2006; Fichtel 2001; Gil 1997; Griffiths 1996; Hicks 2006; Humphreys 2000; Kashikar-Zuck 2005; Kashikar-Zuck 2012; Kroener-Herwig 2002; Labbe 1984; Labbe 1995; Larsson 1987a; Larsson 1987b; Larsson 1990; Larsson 1996; Levy 2010; Palermo 2009; McGrath 1988; McGrath 1992; Osterhaus 1997; Passchier 1990; Richter 1986;Robins 2005; Sanders 1994; Sartory 1998; Scharff 2002; Stinson 2010; Trautmann 2010; van Tilburg 2009; Vlieger 2007; Wicksell 2009). Nine further studies did not meet the inclusion criteria and were excluded (Fentress 1986; Kroener-Herwig 1998; Larsson 1986; Olness 1987;Sanders 1989; Trautmann 2008; Vlieger 2012; Weydert 2006; Youssef 2009).

Included studies

Of the 37 included studies, eight are new to this update (Barakat 2010; Kashikar-Zuck 2012; Levy 2010; Palermo 2009; Stinson 2010; Trautmann 2010; van Tilburg 2009; Wicksell 2009). The total number of participants completing treatments was 1938, 506 more than the previous published analyses. Of the 37 studies, one had four treatment arms, 11 had three arms, and 25 had two arms. The mean number of participants per study at the end of treatment was 52 (sd = 34). Girls outnumbered boys in 26 studies, and boys outnumbered girls in nine, (65% girls, range 22 to 100%). Age was reported in 35 studies (mean = 11.6 years, sd = 4.1 years). Only 16 studies reported the duration of pain, with a mean of 3.8 years.

Participants were recruited from a range of healthcare settings and other sources. Nineteen studies recruited from hospital or clinic settings, four from schools, six from direct advertisement, one study recruited from hospital/clinics and schools, two studies recruited from hospitals and direct advertisements, and five did not report their source. There were 21 studies of treatments for children with headache (including migraine). Of the remainder, seven were for abdominal pain (Alfven 2007; Duarte 2006; Humphreys 2000; Levy 2010; Robins 2005; Sanders 1994; van Tilburg 2009), and one study treated participants with either a primary diagnosis of abdominal pain or a primary diagnosis of irritable bowel syndrome (Vlieger 2007). Two studies treated children with fibromyalgia (Kashikar-Zuck 2005; Kashikar-Zuck 2012), two were for the treatment of pain associated with sickle cell disease (Barakat 2010; Gil 1997) and a further three studies included mixed pain conditions including headache and non-headache pain (Hicks 2006; Palermo 2009; Wicksell 2009) and so were included in both analyses where appropriate. Five study authors provided additional data upon request.

Treatment arms were classified on the basis of their content and of the label given by the study authors. The interventions were categorised into two broad groups. The first is best

described as behavioural, typically relaxation based, with or without biofeedback, and including autogenic or hypnotherapeutic content (Bussone 1998; Fichtel 2001; Labbe 1984; Labbe 1995; Larsson 1987a; Larsson 1987b; Larsson 1990; Larsson 1996; McGrath 1988; McGrath 1992; Passchier 1990; Vlieger 2007). The second is best described as cognitive behavioural therapy, including cognitive coping, coping skills training, and parent operant strategies (Abram 2007; Alfven 2007; Barakat 2010; Barry 1997; Connelly 2006; Duarte 2006; Gil 1997; Griffiths 1996; Hicks 2006; Humphreys 2000; Kashikar-Zuck 2005; Kashikar-Zuck 2012; Kroener-Herwig 2002; Levy 2010; McGrath 1992; Osterhaus 1997; Palermo 2009; Richter 1986; Robins 2005; Sanders 1994; Sartory 1998; Scharff 2002; Stinson 2010; Trautmann 2010; van Tilburg 2009; Wicksell 2009). Different control conditions were employed that were categorised into either active control (e.g. education, $n = 19$) or wait-list/treatment as usual control ($n = 18$). Ten studies reported post-treatment data only; five studies reported follow-up of three months or less and therefore were not included in analyses. Fifteen studies reported follow-up data between three months and a year. Thirty studies reported the treatment length which was typically short in duration ($M = 5.3$ hours for headache studies, $M = 3.5$ hours for non-headache studies, Table 1). Seven studies did not report on the duration of treatment (Alfven 2007; Connelly 2006; Hicks 2006; Humphreys 2000; Kashikar-Zuck 2005; Sartory 1998; Trautmann 2010).

Treatment delivery varied between studies (Table 1). Eighteen studies delivered treatment in a clinic, eight studies delivered treatment at home, of which five used an internet- or computer-based delivery, three were based either in a clinic or at home, so exposure to treatment was uncontrolled. A further three were based in schools, and five were unknown. Home maintenance or practice of treatment was a common and important feature of many studies, but overall treatment exposure including home practice was not reported. Supervised treatment or the introduction of treatment in self-delivery conditions was, however, commonly reported.

Excluded studies

Nine studies were excluded, of which four are new to this update (Trautmann 2008; Vlieger 2012; Weydert 2006; Youssef 2009). Seven had fewer than 10 participants in a treatment arm at the end of treatment (Fentress 1986; Kroener-Herwig 1998; Larsson 1986; Sanders 1989; Trautmann 2008; Weydert 2006; Youssef 2009), one study was judged to have insufficient psychological content in the treatment (Olness 1987), and one study reported only follow-up data of more than one year (Vlieger 2012).

Risk of bias in included studies

All included studies were rated for risk of bias on five categories; random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), and selective reporting (reporting bias) (Figure 1; Figure 2). Thirteen studies were scored as low risk of bias and gave a convincing method of randomisation, a further 24 studies were judged unclear on random sequence generation as they did not provide an adequate method of randomisation. There were none that were scored as having high risk of bias. There were four studies that were judged to have a low risk of bias and gave a convincing method for the allocation, 22 studies that were unclear and 11 studies that had a high risk of bias. Six studies used a third person who was blinded to the group allocation when taking measurements, 31 studies did not report this and so were unclear. Fifteen studies reported attrition fully, reporting that there was no significant difference between completers and non-completers. Seventeen studies only partially reported attrition and so were judged to be unclear and five studies did not report attrition so were judged to have a high risk of bias. Twenty-two studies reported

data fully that could be extracted and used in analyses; 15 studies did not provide full extractable data and were judged to have high risk of bias for selective reporting.

Assessment of quality in included studies

All 37 studies were rated for their quality. For the previously included 29 studies, the quality was rated by two review authors blind to each other's ratings. Intraclass correlation coefficients (absolute agreement) for the two raters on each of the three quality scores (trial quality, study design, and total) ranged from 0.87 for trial quality, 0.89 for study design, and 0.90 for total quality. The quality for the updated eight studies was also rated by two review authors (EF, EL) and disagreements were arbitrated by a third review author (CE) meaning that agreement was met on all items. For the 37 included studies, the mean overall quality of the studies was 20.3 (sd = 5.6, range = 11 to 32). The mean design quality score was 14.4 (sd = 4.1, range = 8 to 23) and the mean treatment quality score was 5.9 (sd = 2.0, range = 2 to 9). The 'Risk of bias' tables' graphics show the overall total quality rating, and summary scores for the quality of the treatment and the quality of the design (Figure 1; Figure 2). A Spearman's correlation was conducted to investigate the association between year of study and treatment quality score, design quality score, and total quality score (sum of treatment quality and design quality). The total quality score was associated with the year of study ($\rho = 0.598$, $P < 0.001$). Treatment quality and design quality were also associated with the year of study ($\rho = 0.596$, $P < 0.001$; $\rho = 0.556$, $P < 0.001$) respectively. Similarly, design quality was associated with treatment quality ($\rho = 0.662$, $P < 0.001$). There were no differences in overall quality, treatment or design quality between headache and non-headache studies. The N at the end of treatment was not associated with total quality score, or design and treatment quality scores when considered independently. This finding remains after accounting for trial complexity (i.e., the number of arms of a trial). Comparing the results of the quality of the studies reported in the previous published review ($n = 29$) and for this update ($n = 8$), those published since Eccleston 2009 are of better overall quality (Mann Whitney $U = 18.5$, $P < 0.001$), treatment quality (Mann Whitney $U = 21.0$, $P < 0.001$) and design quality (Mann Whitney $U = 28.5$, $P < 0.001$). Finally, comparing those published before and since the previous version of this review (Eccleston 2009) there was no significant change in the size of the trial, that is, there was not an increase in the end of treatment N.

Twelve analyses were attempted (pain, disability, and mood outcomes were analysed for headache and non-headache conditions at post-treatment and follow-up). One comparison had only one study contributing and so was excluded. Of the remaining 11 comparisons, five showed low heterogeneity ($I^2 < 25\%$), four showed modest heterogeneity ($I^2 \geq 25\% - < 50\%$) and two showed large heterogeneity ($I^2 \geq 50\%$).

Effects of interventions

See: Summary of findings for the main comparison Psychological therapies for the management of chronic pain (headache) in children and adolescents; Summary of findings 2 Psychological therapies for the management of chronic (non-headache) in children and adolescents

Treatment versus control (headache) post-treatment

Eighteen studies of 748 participants were entered into an analysis of the effects of psychological treatment on pain immediately post-treatment (Barry 1997; Connelly 2006; Fichtel 2001; Griffiths 1996; Hicks 2006; Kroener-Herwig 2002; Labbe 1984; Labbe 1995; Larsson 1987a; Larsson 1987b; Larsson 1990; Larsson 1996; McGrath 1992; Osterhaus 1997; Palermo 2009; Sartory 1998; Scharff 2002; Trautmann 2010). This analysis gave a risk ratio (RR) of 2.90 (95% confidence interval (CI) 2.25 to 3.73; $z = 8.25$, $P < 0.05$) for a

clinically significant change in pain (NNTB = 2.72; CI 2.32 to 3.29) (Figure 3; Figure 4). Three studies of 108 participants were entered into analysis of the effects of treatment on disability (Connelly 2006; Palermo 2009; Wicksell 2009). A small effect was found standardised mean difference (SMD) -0.30 (95% CI -0.85 to 0.24); and this was not significant ($z = 1.09$, $P > 0.05$). Five studies of 204 participants were entered into an analysis of the effects of treatment on mood (Bussone 1998; Griffiths 1996; Palermo 2009; Trautmann 2010; Wicksell 2009). A small effect was found SMD -0.16 (95% CI -0.45 to 0.13); and this was not significant ($z = 1.07$, $P > 0.05$).

Treatment versus control (headache) follow-up

Six studies of 196 participants, were entered into analysis of the effects of treatment on pain at follow-up (Connelly 2006; Hicks 2006; Labbe 1984; Larsson 1987a; Larsson 1987b; Larsson 1996). This analysis gave an RR of 3.34, (95% CI 2.01 to 5.53; $z = 4.68$, $P < 0.05$), for a clinically significant change in pain (NNTB = 2.01; CI 1.62 to 2.64). There was only one study that could be analysed for disability at follow-up (Wicksell 2009), therefore no conclusion could be drawn. Two studies with 59 participants was entered into an analysis of the effects of treatment on mood at follow-up (Bussone 1998; Wicksell 2009) finding a large effect of SMD -0.60 (95% CI -1.13 to -0.07; $z = 2.24$, $P < 0.05$).

Treatment versus control (non-headache) post-treatment

Twelve studies of 709 participants were entered into an analysis of the effects of psychological treatment on continuous pain outcomes immediately post-treatment (Barakat 2010; Hicks 2006; Humphreys 2000; Kashikar-Zuck 2005; Kashikar-Zuck 2012; Levy 2010; Palermo 2009; Robins 2005; Stinson 2010; van Tilburg 2009; Vlieger 2007; Wicksell 2009). A large effect size SMD -0.55 (95% CI -0.84 to -0.26; $z = 3.70$, $P < 0.05$) was found (Figure 5). Nine studies involving 588 participants were entered into analysis of the effects of treatment on disability (Humphreys 2000; Kashikar-Zuck 2005; Kashikar-Zuck 2012; Levy 2010; Palermo 2009; Robins 2005; Stinson 2010; van Tilburg 2009; Wicksell 2009). A small but significant effect was found SMD -0.29 (95% CI -0.49 to -0.10; $z = 2.99$, $P < 0.05$). Six studies of 435 participants were entered into analysis of the effects of treatment on mood (Kashikar-Zuck 2005; Kashikar-Zuck 2012; Levy 2010; Palermo 2009; Stinson 2010; Wicksell 2009). A small effect size was found SMD -0.14 (95% CI -0.42 to 0.15); and this was not significant ($z = 0.92$, $P > 0.05$).

Treatment versus control (non-headache) follow-up

Five studies of 357 participants, had data available for analysis of the effects of treatment on pain at follow-up (Barakat 2010; Hicks 2006; Kashikar-Zuck 2012; Levy 2010; Wicksell 2009). A small effect size was found SMD -0.17 (95% CI -0.60 to 0.26) and this was not significant ($z = 0.77$, $P > 0.05$). Three studies of 292 participants were entered into an analysis of the effects of treatment on disability (Kashikar-Zuck 2012; Levy 2010; Wicksell 2009). A small effect size was found SMD -0.19 (95% CI -0.51 to 0.13) and this was not significant ($z = 1.14$; $P > 0.05$). Three studies of 292 participants were entered into an analysis of the effects of treatment on mood (Kashikar-Zuck 2012; Levy 2010; Wicksell 2009). A small effect size was found SMD -0.09 (95% CI -0.32 to 0.14) and this was not significant ($z = 0.74$, $P > 0.05$).

DISCUSSION

Evidence base

Eight additional studies (end of treatment $n = 506$) were added in this update providing a total of 37 studies and an overall sample of 1938 participants. The outcomes measured and

the categories of measurement remain the same. In multi-arm trials involving more than one treatment or control group, similar treatments or control groups were combined for the purposes of the analyses. The majority of studies used one or two treatment conditions in comparison to a waiting list or standard care control group. Similar to the previous review, the treatments could still be categorised as behavioural or cognitive behavioural although the data were not analysed in this way. The average length of treatment for headache studies was 5.3 hours, and for non-headache studies it was considerably shorter ($M = 3.5$ hours). Follow-up data are increasingly being reported in more recent studies and were included when relevant. The overall quality of the studies has improved since the previous review (Eccleston 2009), although the size of the samples did not increase over time.

The inclusion of further studies has extended the evidence base. Of the 12 possible analyses, five were significant, and three were different from the previous review. Pain intensity was found to improve for headache and non-headache groups at post-treatment, and for the headache group at follow-up. Forty-nine per cent of children with headaches significantly improved their pain scores at post-treatment after receiving psychological therapy compared with only 17% in the control group. However, the addition of more studies to the non-headache pain intensity analysis at follow-up meant this was no longer significant. Disability was significantly improved in non-headache analyses at post-treatment, although the effect size was small. This was also true for mood in the headache group at follow-up. However, this should be interpreted with caution as there were only two studies available for analysis.

Pain intensity was the most common treatment outcome assessed, with 18 studies of children with headache and 12 of children with non-headache pain providing data on pain intensity that could be analysed. An NNTB of 2.72 for psychological therapies to produce more than 50% relief in pain in children with headaches was found. An NNTB of 2.01 was found for the smaller number of trials reporting follow-up. Large effect sizes were also found for reduction in pain intensity in non-headache chronic and recurrent pain at post-treatment. However, the confidence intervals around the effects are large.

Issues for consideration

Further to the previous update, there have been developments in the field which are reflected in the updated trials. All of the new trials used cognitive behavioural therapy compared to purely behavioural therapy. Five of the eight updated studies were non-headache trials, and a further two included mixed samples and so were included in both headache and non-headache analyses. All the updated studies provide data on mood and disability, and four studies provided data that could be entered into the follow-up analyses thereby allowing a better estimate of the maintenance of interventions. Reflecting advances in treatment delivery, four updated studies (six in total) used computer applications (internet and/or CD-ROM) to provide treatment to the children.

In regard to condition, this review included 21 headache studies, seven abdominal pain studies, two sickle cell disease studies, two fibromyalgia studies, four mixed pain studies and one juvenile idiopathic arthritis study. Psychological treatment still appears to have a minimal impact on disability and mood despite reporting two significant effects from this update. Previously, we reported that mood and disability outcomes in trials with children with chronic pain were a focus for trials (McGrath 2008) and this seems to be the case as seven of the eight updated studies had extractable data for disability analyses and five out of eight studies provided extractable data for mood analyses. As these outcomes are being measured and reported more frequently, standardised measurements should be used consistently across the field of paediatric chronic pain and treatments should specifically target changes in these areas.

One limitation of this review is that we are unable to fully discuss the effectiveness of psychological interventions as they were compared with a control group that combined active (e.g. education) and wait-list controls. Just over half the studies used active controls, yet we did not feel that it was an appropriate sample to separate for analysis as has been done in a companion review of treatments for adults with pain (Eccleston 2009a). This limitation may contribute to an overestimation of the treatment effects since it is not possible to separate differences specific to treatment versus active treatment or waiting list control.

AUTHORS' CONCLUSIONS

Implications for practice

Psychological treatments, principally relaxation and cognitive behavioural therapies, are effective treatments of childhood headache pain at post-treatment and follow-up, and mood at follow-up. Behavioural and cognitive behavioural treatments are also effective in reducing non-headache pain, and disability at post-treatment. There is insufficient evidence to explain the effectiveness of psychological interventions for individual non-headache pain conditions due to the limited number of studies for each condition.

Implications for research

Since the original version of this review there has been an improvement in the evidence base by the addition of new studies, and the extension into non-headache pain conditions, and treatments that rely on more complex methods. This update adds studies to the previous review so readers are able to understand the effects that psychological interventions have for headache and non-headache pain. However, this structure limits our understanding of whether psychological therapies are unique in their improvement of symptoms in comparison to active or wait-list control groups, yet we felt this was important to present before introducing further analyses. The author team are considering the following possible changes for the next version of the review.

1. Increasing the current criterion of 10 participants in both the treatment and control groups at the point of analysis, to 20.
2. Splitting the title into two titles: one based on headache only and one based on treatment for non-headache disorders.
3. Introducing sub-group analysis to focus on critical issues in therapy such as type of therapy, dose of therapy, location of therapy, and involvement of other quasi therapeutic agents (e.g., parents).

Measurement

Measurement of non-pain outcomes is increasing and should continue to be included and reported in trials with children and adolescents. Recommendations are now available with regards to evidence based assessment of relevant domains for trials of chronic and recurrent pain in children (McGrath 2008). Measures have been developed to assess the majority of these domains. However, additional validation work is needed particularly on child disability outcome measures. Currently available measures have several limitations including a lack of data on sensitivity to change and factor structure, and do not have established cut-off scores to aid in interpretation of scores as situated in the clinical versus normative range (Palermo 2008). It is currently unclear whether treatments might be effective at changing particular aspects of disability because the measures lump together various concepts such as vigorous physical activity, role functioning (e.g., school attendance), and regular activity participation. Future validation work may help disentangle this complex and multidimensional domain.

Treatment

Studies in this review are dominated by behavioural or cognitive behavioural treatments. However, more recent studies show a shift towards cognitive behavioural therapy. There is now a call for more varied psychological therapies that have been used in other paediatric chronic illnesses such as diabetes (multisystemic therapy), cancer (problem-solving therapy) and asthma (family therapy). Such therapies in painful conditions would give a broader understanding of which therapies can work for a particular population. There is also a need for more trials in non-headache conditions as we are as yet unable to understand the effectiveness of psychological interventions in specific conditions such as sickle cell disease. There have been developments in the delivery of treatments with technology advances. Five trials delivered their therapy using a computer- or internet-based programme (Connelly 2006; Hicks 2006; Palermo 2009; Trautmann 2010; Wicksell 2009). This delivery mode has the ability to reach more patients quicker, and in this digital age, these treatments are fast becoming the most accessible. As reported in the previous review, important information is still lacking in trials such as treatment expectations, treatment history, baseline pain and disability which is important to understand how and why some treatments are more effective than others. Similarly, treatment response is precluded by individual differences of the trials and samples, such as small sample sizes, mixed illness groups and wide age ranges included in the current trials.

Trial design

Trials have improved in quality and updated trials include follow-up periods so we are better able to understand the maintenance of treatment effects. However, the number of participants entering treatments is still small and should be increased in future trials, and multi-site collaboration is needed to achieve this. More trials are needed in non-headache pain conditions so as to determine the effectiveness of psychological therapies for individual conditions. Therapies should also be tailored to the child and families' needs, and sociodemographic differences should be explored and reported. Treatments delivered are to date dominated by behavioural or cognitive behavioural therapy. Future trials should expand beyond these therapy groups to identify if other therapies are effective for chronic pain conditions and all treatments should include specific content to improve disability and mood. Finally, new trials should use active comparators over wait-list control groups.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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- No sources of support supplied

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* *Indicates the major publication for the study*

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APPENDICES

Appendix 1. Search Strategies

Medline via Ovid search strategy

1. exp child/
2. Infant/
3. Adolescent/
4. (child\$ or adolescent\$ or infant\$ or juvenil\$ or pediatric\$ or paediatric\$ or “young person\$” or “young people” or youth\$ or “young adult\$”).ab,ti,kf.
5. 1 or 2 or 3 or 4
6. exp Psychology/
7. exp Psychotherapy/
8. exp Behavior Therapy/
9. (psycholog\$ or (behavio?r and therapy) or hypnos\$ or relaxation\$ or ((family or color or colour or music or play) adj therap\$) or imagery or cogniti\$ or psychotherap\$).ab,ti,kf.
10. 6 or 7 or 8 or 9
11. (pain\$ or headache\$ or “headache\$” or head-ache\$ or migraine\$ or cephalalg\$ or “stomachache\$” or “tummy ache\$” or “abdominal ache\$” or “belly ache\$” or earache\$ or ear-ache\$ or toothache\$ or tooth-ache\$ or odontalg\$ or dysmenorrh\$ or neuralgi\$).ab,ti,kf.
12. exp Pain/
13. exp Headache Disorders/
14. 11 or 12 or 13
15. 5 and 10 and 14

Cochrane sensitive search strategy filter for RCTs (OVID version for MEDLINE searches)

Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11 and detailed in boxes 6.4.c of The *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.0 [updated February 2008].

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.

4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1–8
10. humans.sh.
11. 9 and 10

EMBASE via Ovid search strategy

1. Child/
2. Infant/
3. Adolescent/
4. (child\$ or adolescent\$ or infant\$ or juvenil\$ or pediatric\$ or paediatric\$ or “young person\$” or “young people” or youth\$ or “young adult\$”).ab,ti.
5. 1 or 2 or 3 or 4
6. exp PSYCHOLOGY/
7. exp PSYCHOTHERAPY/
8. behavior therapy/
9. (psycholog\$ or (behavio?r and therapy) or hypnos\$ or relaxation\$ or ((family or color or colour or music or play) adj therap\$) or imagery or cogniti\$ or psychotherap\$).ab,ti.
10. 6 or 7 or 8 or 9
11. (pain\$ or headache\$ or “headache\$” or head-ache\$ or migraine\$ or cephalalgi\$ or “stomachache\$” or “tummy ache\$” or “abdominal ache\$” or “belly ache\$” or earache\$ or ear-ache\$ or toothache\$ or tooth-ache\$ or odontalgi\$ or dysmenorrh\$ or neuralgi\$).ab,ti.
12. exp Pain/
13. exp “Headache and Facial Pain”/
14. 11 or 12 or 13
15. 5 and 10 and 14

The above subject search was linked to the following filter for EMBASE via OVID

1. random\$.ti,ab.
2. factorial\$.ti,ab.
3. (crossover\$ or cross over\$ or cross-over\$).ti,ab.
4. placebo\$.ti,ab.
5. (doubl\$ adj blind\$).ti,ab.
6. (singl\$ adj blind\$).ti,ab.

7. assign\$.ti,ab.
8. allocat\$.ti,ab.
9. volunteer\$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1–13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

PsychInfo via OVID

1. (child\$ or adolescent\$ or infant\$ or juvenil\$ or pediatric\$ or paediatric\$ or “young person\$” or “young people” or youth\$ or “young adult\$”).ab,ti.
2. exp PSYCHOLOGY/
3. exp PSYCHOTHERAPY/
4. behavior therapy/
5. (psycholog\$ or (behavio?r and therapy) or hypnos\$ or relaxation\$ or ((family or color or colour or music or play) adj therap\$) or imagery or cogniti\$ or psychotherap\$).ab,ti.
6. 2 or 3 or 4 or 5
7. (pain\$ or headache\$ or “head ache\$” or head-ache\$ or migraine\$ or cephalalg\$ or “stomach ache\$” or “tummy ache\$” or “abdominal ache\$” or “belly ache\$” or earache\$ or ear-ache\$ or toothache\$ or tooth-ache\$ or odontalg\$ or dysmenorrh\$ or neuralgi\$).ab,ti.
8. exp Pain/
9. Headache/
10. Migraine Headache/
11. Muscle Contraction Headache/
12. 7 or 8 or 9 or 10 or 11
13. 1 and 6 and 12

WHAT'S NEW

Last assessed as up-to-date: 12 November 2012.

Date	Event	Description
24 October 2012	New search has been performed	New authors have been added to this review. A new search was run in March 2012. Eight new studies were added (Barakat 2010; Kashikar-Zuck 2012; Levy 2010; Palermo 2009; Stinson 2010; Trautmann 2010; van Tilburg 2009; Wicksell 2009), and four new studies were excluded (Trautmann 2008; Vlieger 2012; Weydert 2006; Youssef 2009).
24 October 2012	New citation required and conclusions have changed	The previous review reported psychological treatments were effective for headache and non-headache groups at post-treatment and effects were maintained at follow-up. Updated studies have altered previous results. The current update found pain improved at post-treatment for headache and non-headache groups, and for headache groups at follow-up. An additional significant finding for disability at post-treatment for the non-headache group was found. Conclusions have been updated accordingly

Figure 1.
Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Abram 2007	?	?	?	?	?
Alfven 2007	?	?	?	?	?
Barakat 2010	?	?	?	?	?
Barry 1997	?	?	?	?	?
Bussone 1998	?	?	?	?	?
Connelly 2006	?	?	?	?	?
Duarte 2006	?	?	?	?	?
Fichtel 2001	?	?	?	?	?
Gil 1997	?	?	?	?	?
Griffiths 1996	?	?	?	?	?
Hicks 2006	?	?	?	?	?
Humphreys 2000	?	?	?	?	?
Kashikar-Zuck 2005	?	?	?	?	?
Kashikar-Zuck 2012	?	?	?	?	?
Kroener-Herwig 2002	?	?	?	?	?
Labbe 1984	?	?	?	?	?
Labbe 1995	?	?	?	?	?
Larsson 1987a	?	?	?	?	?
Larsson 1987b	?	?	?	?	?
Larsson 1990	?	?	?	?	?
Larsson 1996	?	?	?	?	?
Levy 2010	?	?	?	?	?
McGrath 1988	?	?	?	?	?
McGrath 1992	?	?	?	?	?
Osterhaus 1997	?	?	?	?	?
Palermo 2009	?	?	?	?	?
Passchier 1990	?	?	?	?	?
Richter 1986	?	?	?	?	?
Robins 2005	?	?	?	?	?
Sanders 1994	?	?	?	?	?
Sartory 1998	?	?	?	?	?
Scharff 2002	?	?	?	?	?
Stinson 2010	?	?	?	?	?
Trautmann 2010	?	?	?	?	?
van Tilburg 2009	?	?	?	?	?
Vlieger 2007	?	?	?	?	?
Wicksell 2009	?	?	?	?	?

Figure 2.

Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Figure 3.
Forest plot of comparison: 1 Treatment vs control (headache) post-treatment, outcome: 1.1 Pain.

Figure 4.

Figure 5.
 Forest plot of comparison: 3 Treatment vs control (non-headache) post-treatment, outcome:
 3.1 Pain.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 1 Treatment versus control (headache) post-treatment.

Outcome: 1 Pain

Analysis 1.1.

Comparison 1 Treatment versus control (headache) post-treatment., Outcome 1 Pain.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 1 Treatment versus control (headache) post-treatment.

Outcome: 2 Disability

Analysis 1.2.

Comparison 1 Treatment versus control (headache) post-treatment., Outcome 2 Disability.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 1 Treatment versus control (headache) post-treatment.

Outcome: 3 Mood

Analysis 1.3.

Comparison 1 Treatment versus control (headache) post-treatment., Outcome 3 Mood.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 2 Treatment versus control (headache) follow-up

Outcome: 1 Pain

Analysis 2.1.

Comparison 2 Treatment versus control (headache) follow-up, Outcome 1 Pain.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 2 Treatment versus control (headache) follow-up

Outcome: 2 Disability

Analysis 2.2.

Comparison 2 Treatment versus control (headache) follow-up, Outcome 2 Disability.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 2 Treatment versus control (headache) follow-up

Outcome: 3 Mood

Analysis 2.3.

Comparison 2 Treatment versus control (headache) follow-up, Outcome 3 Mood.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 3 Treatment versus control (non-headache) post-treatment

Outcome: 1 Pain

Analysis 3.1.

Comparison 3 Treatment versus control (non-headache) post-treatment, Outcome 1 Pain.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 3 Treatment versus control (non-headache) post-treatment

Outcome: 2 Disability

Analysis 3.2.

Comparison 3 Treatment versus control (non-headache) post-treatment, Outcome 2 Disability.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 3 Treatment versus control (non-headache) post-treatment

Outcome: 3 Mood

Analysis 3.3.

Comparison 3 Treatment versus control (non-headache) post-treatment, Outcome 3 Mood.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 4 Treatment versus control (non-headache) follow-up

Outcome: 1 Pain

Analysis 4.1.

Comparison 4 Treatment versus control (non-headache) follow-up, Outcome 1 Pain.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 4 Treatment versus control (non-headache) follow-up

Outcome: 2 Disability

Analysis 4.2.

Comparison 4 Treatment versus control (non-headache) follow-up, Outcome 2 Disability.

Review: Psychological therapies for the management of chronic and recurrent pain in children and adolescents

Comparison: 4 Treatment versus control (non-headache) follow-up

Outcome: 3 Mood

Analysis 4.3.

Comparison 4 Treatment versus control (non-headache) follow-up, Outcome 3 Mood.

Table 1

Duration of treatment and setting by condition

Headache studies			
Author	Illness	Treatment duration (Hrs)	Setting
Abram 2007	Headache	1.5	Clinic
Barry 1997	Headache	3	Unknown
Bussone 1998	Headache	7	Clinic
Connelly 2006	Headache	Unknown	Home - CDROM
Fichtel 2001	Headache	6.75	Clinic
Griffiths 1996	Headache	12	Clinic/Home
Hicks 2006 *	Mixed	Unknown	Home - Internet
Kroener-Herwig 2002	Headache	12	Clinic
Labbe 1984	Headache	6.7	Clinic
Labbe 1995	Headache	7.5	Clinic
Larsson 1987a	Headache	6.75	School
Larsson 1987b	Headache	5	School
Larsson 1990	Headache	1.7	Home
Larsson 1996	Headache	3.3	Clinic
McGrath 1988	Headache	6	Unknown
McGrath 1992	Headache	8	Home/Clinic
Osterhaus 1997	Headache	9.3	Clinic
Palermo 2009 *	Mixed	4	Home - Internet
Passchier 1990	Headache	2.5	School
Richter 1986	Headache	9	Unknown
Sartory 1998	Headache	Unknown	Clinic
Scharff 2002	Headache	4	Clinic
Trautmann 2010	Headache	Unknown	Home - Internet
Wicksell 2009 *	Mixed	10	Clinic

Non-headache studies			
Author	Illness	Treatment duration (Hrs)	Setting
Alfven 2007	RAP	Unknown	Clinic
Barakat 2010	SCD	6	Home
Duarte 2006	RAP	3.3	Unknown
Gil 1997	SCD	0.75	Clinic
Hicks 2006 *	Headache + RAP	Unknown	Home - Internet
Humphreys 2000	RAP	Unknown	Clinic
Kashikar-Zuck 2005	Fibromyalgia	Unknown	Clinic
Kashikar-Zuck 2012	Fibromyalgia	6	Unknown
Levy 2010	RAP	4	Home/Clinic

Non-headache studies

Author	Illness	Treatment duration (Hrs)	Setting
Palermo 2009 *	Mixed	4	Home - Internet
Robins 2005	RAP	3.5	Clinic
Sanders 1994	RAP	6	Clinic
Stinson 2010	JIA	5	Home - Internet
an Tilburg 2009	RAP	1.8	Home
Vlieger 2007	RAP/IBS	5	Clinic
Wicksell 2009 *	Mixed	10	Clinic

* Mixed headache and non-headache studies are entered twice. Recurrent abdominal pain (RAP), Sickle cell disease (SCD), Juvenile idiopathic arthritis (JIA), Irritable bowel syndrome (IBS).

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Psychological therapies for the management of chronic pain (headache) in children and adolescents						
Patient or population: Children and adolescents with chronic headache						
Settings: Community and secondary care						
Intervention: Psychological therapies						
Outcomes	Illustrative probable outcomes* (95% CI)		Relative effect (95% CI) and NNT	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Probable outcome within control	Probable outcome within intervention				
	Psychological therapies					
	Control					
Pain	170 per 1000	492 per 1000 (381 to 632)	RR 2.9 (2.25 to 3.73) NNT 2.72 (2.32 to 3.29)	748 (18 studies)	⊕⊕⊕⊕ Moderate ^{1,2}	Results were statistically significant
Pain (at follow-up)	167 per 1000	400 per 1000 (287 to 525)	RR 2.4 (1.72 to 3.15) NNT 2.01 (1.62 to 2.64)	196 (6 studies)	⊕⊕⊕⊕ Low ^{1,3,4}	Results were statistically significant
Disability	The mean disability in the intervention groups was 0.3 standard deviations lower (0.85 lower to 0.24 higher)			108 (3 studies)	⊕⊕⊕⊕ Moderate ⁵	SMD -0.3 (-0.85 to 0.24) Results were not significant
Disability (at follow-up)	The mean disability (at follow-up) in the intervention groups was 0.45 standard deviations lower (1.27 lower to 0.36 higher)			24 (1 study)	⊕⊕⊕⊕ Low ³	SMD -0.45 (-1.27 to 0.36) Insufficient evidence to draw conclusions
Mood	The mean mood in the intervention groups was 0.07 standard deviations higher (0.3 lower to 0.45 higher)			204 (5 studies)	⊕⊕⊕⊕ High	SMD 0.07 (-0.3 to 0.45) Results were not significant

Mood (at follow-up)	The mean mood (at follow-up) in the intervention groups was 0.57 standard deviations lower (1.09 to 0.04 lower)	59 (2 studies)	⊕⊕⊕⊕ Moderate ³	SMD -0.57 (-1.09 to -0.04) Insufficient evidence to draw conclusions
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*The basis for the **probable outcome within control** (e.g. the median control group risk across studies) is provided in footnotes. The **probable outcome within intervention** (and its 95% confidence interval) is based on the probable outcome within the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR**: Risk ratio; **NNT**: Numbers needed to treat

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

Assessments were made following guidance from the Cochrane Handbook (Higgins 2011). Outcomes were marked on five categories; Limitations in the design and implementation, indirectness of evidence, limitations in the design and implementation, unexplained heterogeneity or inconsistency of results, and high probability of publication bias. Outcomes were downgraded to moderate if they were marked down in one category, and to 'low' if they were marked down in more than one category. This is with the exception of 'Disability at follow-up' which was marked 'low' due to only having one study within the analysis.

- ¹Limitations in the design and implementation: proportion of studies had poor descriptions of randomisation
- ²Limitations in the design and implementation: proportion of studies did not report follow-up data. Unclear whether earlier studies used ITT analyses
- ³Imprecision of results: small sample sizes
- ⁴Unexplained heterogeneity or inconsistency of results: wide confidence intervals
- ⁵Unexplained heterogeneity or inconsistency of results: I squared = > 45%, Heterogeneity Tau = P > 0.05, variation can be explained

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Psychological therapies for the management of chronic (non-headache) in children and adolescents					
Patient or population: Children and adolescents with chronic pain (non-headache) Settings: Community and secondary care Intervention: Psychological therapies					
Outcomes	Illustrative probable outcomes* (95% CI)	Relative effect (95% CI) and NNT	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
<div> <div>Probable outcome within control</div> <div>Psychological therapies</div> </div>					
Pain	The mean pain in the intervention groups was 0.51 standard deviations lower (0.8 to 0.22 lower)		709 (12 studies)	⊕⊕⊕⊕ Moderate	SMD -0.51 (-0.8 to -0.22) Results were statistically significant
Pain (at follow-up)	The mean pain (at follow-up) in the intervention groups was 0.17 standard deviations lower (0.6 lower to 0.26 higher)		357 (5 studies)	⊕⊕⊕⊕ Moderate	SMD -0.17 (-0.6 to 0.26) Results were not statistically significant
Disability	The mean disability in the intervention groups was 0.27 standard deviations lower (0.45 to 0.08 lower)		625 (10 studies)	⊕⊕⊕⊕⊕ High	SMD -0.27 (-0.45 to -0.08) Results were statistically significant
Disability (at follow-up)	The mean disability (at follow-up) in the intervention groups was 0.11 standard deviations lower (0.43 lower to 0.21 higher)		325 (4 studies)	⊕⊕⊕⊕ High	SMD -0.11 (-0.43 to 0.21) Results were not significant
Mood	The mean mood in the intervention groups was 0.14 standard deviations		435 (6 studies)	⊕⊕⊕⊕ Moderate	SMD -0.14 (-0.42 to 0.14)

15) Results were not significant							
lower (0.42 lower to 0.15 higher)							
The mean mood (at follow-up) in the intervention groups was							
0.09 standard deviations lower (0.32 lower to 0.14 higher)							

*The basis for the **probable outcome within control** (e.g. the median control group risk across studies) is provided in footnotes. The **probable outcome within intervention** (and its 95% confidence interval) is based on the probable outcome within the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR**: Risk ratio; **NNT**: Numbers needed to treat

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

GRADE assessments were made following guidance from the Cochrane Handbook (Higgins 2011). Outcomes were marked on five categories: Limitations in the design and implementation, indirectness of evidence, limitations in the design and implementation, unexplained heterogeneity or inconsistency of results, and high probability of publication bias. Outcomes were downgraded to moderate if they were marked down in one category, and to 'low' if they were marked down in more than one category. This is with the exception of 'Disability at follow-up' which was marked 'low' due to only having one study within the analysis.

¹Unexplained heterogeneity or inconsistency of results: I squared = > 45%, Heterogeneity Tau = P > 0.05, variance can be explained

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abram 2007

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment (three month follow-up), six months
Participants	End of treatment n = 50 Start of treatment n = 81 Sex: 45F, 36M Mean age = 12.7 (range 10–18) Source = Hospital and Clinic Diagnosis = Headache Mean years of pain = not given
Interventions	“Headache Clinical Model: behavioural intervention” “Headache Traditional Model: consultation with neurologist”
Outcomes	Primary Pain Outcome: none Primary Disability Outcome: Ped-MIDAS Primary Mood Outcome: none 1. Pediatric Migraine Disability Assessment (Ped-MIDAS) 2. FDI-C 3. Headache Knowledge test 4. Use of Healthcare measure
Notes	Updated Study 2009 Total Quality = 22/35 Treatment Quality = 7/9 Design Quality = 15/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'If the family was interested in the study, they were randomised (using a random number table) to either a TCM appointment or a HCM appointment.' Comment: Probably done
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however no significant descriptions between completers and non-completers were reported
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Alfven 2007

Methods	RCT. Two arms. Assessed at pre-treatment and one-year follow-up
Participants	End of treatment n = 48 Start of treatment n = 48 Sex: 61F, 22M (Of entire sample in three treatment conditions, one post randomisation) Mean age = 9.9 (range 6–18) Source = Hospital Diagnosis = Recurrent Abdominal Pain Mean years of pain = 2.5
Interventions	“psychological treatment and physiotherapy” “Physiotherapy alone”
Outcomes	Primary Pain Outcome: Pain score Primary Disability Outcome: none Primary Mood Outcome: none 1. Pain intensity (VAS) 2. Pain Score a) frequency b) intensity c) duration 3. Tender points (algometer)
Notes	Updated Study 2009 Total Quality = 13/35 Treatment Quality = 2/9 Design Quality = 11/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The children recruited during 1996–1999 were randomised'. Comment: probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts reported.
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Barakat 2010

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment and twelve months
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Barakat 2010

Participants	End of treatment n = 42, Follow-up 1 year n = 34 Start of treatment n = 42 Sex: 12F, 15M Mean age = 14.17 (1.75) Source = Sickle cell centre Diagnosis = Sickle Cell Disease Mean years of pain = Lifetime
Interventions	"Pain Management Intervention" "Disease Education Intervention"
Outcomes	Primary Pain Outcome: Pain Diary Primary Disability Outcome: none Primary Mood Outcome: none 1. Pain Diary 2. Health-related Hindrance Inventory 3. Child Health Questionnaire 4. Family Cohesion Scale 5. Disease Self-efficacy Scale 6. Coping Strategies Inventory 7. SCD Transition Knowledge Questionnaire 8. Medical Chart Review 9. School Attendance
Notes	Updated study 2012 Total Quality = 27/35 Treatment Quality = 9/9 Design Quality = 18/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'A 2-group, randomized treatment design was used.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, no significant descriptions between completers and non-completers were reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Barry 1997

Barry 1997

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, three months
Participants	<p>End of treatment n = 29</p> <p>Start of treatment n = 36</p> <p>Sex: 19F, 10M</p> <p>Mean age = 9.4</p> <p>Source = Volunteers via school & primary healthcare settings; referrals invited from primary and secondary care</p> <p>Diagnosis = Headache</p> <p>Mean years of pain not given</p>
Interventions	<p>"Cognitive behaviour therapy"</p> <p>"Waiting list control"</p>
Outcomes	<p>Primary Pain Outcome: Headache intensity</p> <p>Primary Disability Outcome: School absence</p> <p>Primary Mood Outcome: none</p> <ol style="list-style-type: none"> 1. Headache intensity 2. Headache duration 3. Mood 4. School absence due to headache 5. Activities missed due to headache 6. Medication intake 7. Pain management strategies used
Notes	<p>Original Study</p> <p>Total Quality = 14/35</p> <p>Treatment Quality = 3/9</p> <p>Design Quality = 11/26</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Each parent-child pair was initially matched with another pair based on the child's age, sex and headache pain as indicated by the parents' ratings of average duration, frequency, and intensity of headaches. Subsequently, one of each of them matched parent-child pairs was randomly assigned to either the treatment condition or the waiting list control condition. ' Comment: Probably done, method not described
Allocation concealment (selection bias)	High risk	'Each parent-child pair was initially matched with another pair based on the child's age, sex and headache pain as indicated by the parents' ratings of average duration, frequency, and intensity of headaches. Subsequently, one of each of them matched parent-child pairs was randomly assigned to either the treatment condition or the waiting list control condition. ' Comment: Probably done

Barry 1997

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, no significant descriptions between completers and non-completers were reported
Selective reporting (reporting bias)	High risk	Data was incompletely reported.

Bussone 1998

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, six months, 12 months	
Participants	End of Treatment n = 35 Start of Treatment n = 35 Sex: 17F, 18M Mean age = 11.4 (range 11–15) Source = Specialised headache clinic Diagnosis = Headache Mean years of pain (mean) = 2.6	
Interventions	“Biofeedback (assisted relaxation)” “Relaxation”	
Outcomes	Primary Pain Outcome: Pain index Primary Disability Outcome: none Primary Mood Outcome: Anxiety (STAI) 1. Pain Total Index (Headache Diary) 2. State Trait Anxiety Index (STAI) 3. Analgesic use	
Notes	Updated Study 2009 Total Quality = 18/35 Treatment Quality = 5/9 Design Quality = 13/26	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Patients were randomly assigned to one of two experimental conditions'. Comment: Probably done, method not described
Allocation concealment (selection bias)	High risk	'...with the constraint that subjects be over-sampled in BFB-REL treatment (2:1 ratio) in order to make actual treatment available to as many children as possible.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.

Bussone 1998

Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts reported in study.
Selective reporting (reporting bias)	High risk	Data incompletely reported.

Connelly 2006

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, two months, three months	
Participants	End of Treatment n = 36 Start of treatment n = 37 Sex: 18F, 19M Mean age = 10.0 (range 7–12) Source = Clinic Diagnosis = Headache Mean years of pain = not given	
Interventions	“CD-ROM behavioural” “Wait-list neurology TAU”	
Outcomes	Primary Pain Outcome: Headache diary Primary Disability Outcome: Ped-MIDAS Primary Mood Outcome: none 1. Total Pain (Headache diary) 2. Pediatric Migraine Disability Assessment (Ped-MIDAS)	
Notes	Updated Study 2009 Total Quality = 24/35 Treatment Quality = 8/9 Design Quality = 16/26	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomly assigned to one of two groups by a research assistant using a uniform random numbers table.' Comment: Probably done
Allocation concealment (selection bias)	Low risk	'Randomly assigned to one of two groups by a research assistant using a uniform random numbers table.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Study neurologists remained blind to randomisation condition throughout the study. Chance of unbinding were limited because follow-up appointments with the study neurologist were scheduled for 2 months following the initial assessment.' Comment: probably done
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant descriptions between completers and non-completers was not reported

Connelly 2006

Selective reporting (reporting bias)	Low risk	Data were fully reported.
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Duarte 2006

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment
Participants	End of Treatment n = 32 Start of Treatment n = 32 Sex: 22F, 10M Mean age = 9.1 (sd 2.1) Source = Paediatric gastroenterology service Diagnosis = Recurrent abdominal pain Mean years of pain = 2.1
Interventions	“Cognitive behavioural family intervention” “Standard paediatric care, 4 sessions”
Outcomes	Primary Pain Outcome: pain intensity VAS Primary Disability Outcome: none Primary Mood Outcome: none 1. Pain VAS (reduced to 4 categories), completed daily 2. Parent estimate of frequency over last month 3. Pressure point threshold using algometer
Notes	Updated Study 2009 Total Quality = 15/35 Treatment Quality = 5/9 Design Quality = 10/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomly allocated to 2 groups.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported in the study.
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Fichtel 2001

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, eight-12 months
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Fichtel 2001

Participants	End of Treatment n = 36 Start of Treatment n = 36 Sex: 25F, 11M Mean age =15.4 (range 13–18) Source = School Diagnosis = Headache Mean years of pain = not given
Interventions	“Relaxation” “Waiting List Control”
Outcomes	Primary Pain Outcome: Total headache score Primary Disability Outcome: none Primary Mood Outcome: none 1. Total headache score (Headache diary) 2. Medication consumption
Notes	Updated Study 2009 Total Quality = 15/35 Treatment Quality = 4/9 Design Quality = 11/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The subjects were randomly assigned to the relaxation treatment or waiting list groups'. Comment: Probably done, no method is described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported in the study.
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Gil 1997

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment.
Participants	End of Treatment n = 49 Start of treatment n = 49 Sex: 23F, 26M Mean age =11.9 Source = University medical centre sickle cell centre

Gil 1997

	Diagnosis = Sickle cell anaemia (SS), sickle cell disease (SC), sickle beta thalassaemia Mean years of pain = not given
Interventions	“Cognitive coping skills” “Standard care control”
Outcomes	Primary Pain Outcome: none Primary Disability Outcome: none Primary Mood Outcome: none 1. Pain sensitivity (pressure stimulator) 2. Coping strategy questionnaire 3. Disease severity: acute and chronic complications in past 12 months
Notes	Original Study Total Quality = 16/35 Treatment Quality = 8/9 Design Quality = 8/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Participants were then randomly assigned to one of two conditions.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts reported in study.
Selective reporting (reporting bias)	High risk	Data not fully reported.

Griffiths 1996

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment and nine weeks post-treatment
Participants	End of Treatment n = 42, Follow-up n = 42 Start of Treatment n = 51 Sex: 21F, 21M Mean age = 11.3 Source = Not known Diagnosis = Migraine Mean years of pain = not given: minimum 6 months
Interventions	“Cognitive behavioural therapy (clinic based)” “cognitive behavioural therapy (home based)”

Griffiths 1996

	“Self monitoring”
Outcomes	Primary Pain Outcome: headache index Primary Disability Outcome: none Primary Mood Outcome: Child Depression Scale 1. Headache index (averaged intensity) 2. Medication used 3. Child Manifest Anxiety Scale (CMAS) 4. Children’s Depression Scale (CDS) 5. Self-efficacy 6. Coping responses from Children’s Headache Assessment Scale (CHAS)
Notes	Original Study Total Quality = 18/35 Treatment Quality = 5/9 Design Quality = 13/26

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	‘It was decided to assign children to groups by true randomisation rather than on the basis of headache diagnosis’. Comment: Probably done, no method is described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was not described.
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Hicks 2006

Methods	RCT. Two arms. Assessed at pre-treatment, one month post-treatment, three months
Participants	End of Treatment n = 37, one-month follow-up = 37, three-month follow-up = 32 Start of Treatment n = 47 Sex: 30F, 17M Mean age = 11.7 (range 9–16) Source = Advertisements in media, physicians’ offices and school Diagnosis = Headache and RAP Duration (mean): three years.
Interventions	“Internet CBT (with internet and phone)” “Standard Care (Wait List)”

Hicks 2006

Outcomes	Primary Pain Outcome: Total Pain Score Primary Disability Outcome: none Primary Mood Outcome: none 1. Pain diary 2. NRS frequency 3. NRS intensity 4. PEDSQL 5. Parental Quality of Life
Notes	Updated Study 2009 Total Quality = 27/35 Treatment Quality = 8/9 Design Quality = 19/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'The 47 participants were stratified by age and pain severity and randomly assigned by blocks to either the treatment condition or the standard medical care wait-list condition.' Comment: Probably done
Allocation concealment (selection bias)	Low risk	'The 47 participants were stratified by age and pain severity and randomly assigned by blocks to either the treatment condition or the standard medical care wait-list condition.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is described, no significant descriptions between completers and non-completers were reported
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Humphreys 2000

Methods	RCT. Four arms. Assessed at pre-treatment, post-treatment
Participants	End of Treatment n = 61 Start of Treatment n = 64 Sex: 38F, 26M Mean age = 9.8 (sd 2.5) Source = Advertisement + physician referral Diagnosis = Recurrent Abdominal Pain Mean years of pain = None given
Interventions	"CBT + biofeedback + parental support + fibre" "CBT + biofeedback + fibre"

Humphreys 2000

	“Biofeedback + fibre” “fibre”
Outcomes	Primary Pain Outcome: Pain Diary Primary Disability Outcome: School Attendance Primary Mood Outcome: None 1. Child Pain Diary 2. Parental Observation Record 3. Health Care Utilisation Record 4. Medical Record 5. School attendance
Notes	Updated Study 2009 Total Quality = 14/35 Treatment Quality = 5/9 Design Quality = 9/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Patients were randomly assigned to one of the four groups'. Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition not described, significant differences between completers and non-completers no reported
Selective reporting (reporting bias)	Low risk	Data fully reported.

Kashikar-Zuck 2005

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment (week 8), six weeks
Participants	End of treatment n = 27 Start of Treatment n = 30 Sex: 30F, 0M Median age = 15.8 (sd 1.3) Source = Paediatric rheumatology clinic of children's hospital Diagnosis = Juvenile primary fibromyalgia (JPFM criteria; Yunus) Mean years of pain = 19 for > 2 years, 11 for 6 months to 2 years
Interventions	“Coping skills training” “Self-monitoring”

Kashikar-Zuck 2005

Outcomes	Primary Pain Outcome: Average pain VAS Primary Disability Outcome: Functional Disability Inventory Primary Mood Outcome: Children's Depression Inventory 1. Average pain VAS 0–100 2. Highest pain VAS 0–100 3. Functional Disability Inventory (FDI) 4. Children's Depression Inventory (CDI) 5. Pain Coping Questionnaire (PCQ) 6. Pain Coping Efficacy (items from PCQ) 7. Tender points
Notes	Updated Study 2009 Total Quality = 25/35 Treatment Quality = 7/9 Design Quality = 18/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'A computer generated pseudo-random number list was used. A simple randomisation technique was used with a 1:1 allocation ratio for 30 subjects as a single block.' Comment: Probably done
Allocation concealment (selection bias)	Low risk	'A computer generated pseudo-random number list was used. A simple randomisation technique was used with a 1:1 allocation ratio for 30 subjects as a single block.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'A research assistant who was blind to the study objectives and to the subjects' treatment assignment administered the self-report measures. The rheumatologist or occupational therapist who conducted the tender point assessments was blind to the subjects' treatment assignment.' Comment: Probably done
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant descriptions between completers and non-completers was not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Kashikar-Zuck 2012

Methods	RCT. Two arms. Assessed pre-treatment, post-treatment, six-month follow-up
Participants	End of treatment n = 106, Follow-up six months n = 100 Start of treatment n = 114 Sex: 105F, 9M Mean age = 15.0 (1.8) Source = Paediatric rheumatology centres in Midwestern USA

Kashikar-Zuck 2012

	Diagnosis = Fibromyalgia Syndrome Mean years of pain = two years, 10 months (2yrs, 6mth)
Interventions	“Cognitive behavioural therapy” “Fibromyalgia education”
Outcomes	Primary Pain Outcome: Pain Severity VAS (averaged over seven days) Primary Disability Outcome: Functional Disability Scale Primary Mood Outcome: Children’s Depression Inventory 1. Pain severity VAS (averaged over seven days) 2. Functional Disability Scale 3. Children’s Depression Inventory 4. Tender point sensitivity 5. Pediatric Quality of Life Inventory 6. Sleep quality VAS (averaged over seven days) 7. Physician’s global assessment VAS
Notes	Updated Study 2012 Total Quality = 32/35 Treatment Quality = 9/9 Design Quality = 23/26

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	‘Eligible patients were randomly assigned to 1 of the 2 treatment arms based upon a computer-generated randomisation list. Randomisation was stratified by site.’ Comment: probably done
Allocation concealment (selection bias)	Low risk	‘When a patient was enrolled, the study therapist contacted the biostatistician to obtain the subject identification number and treatment allocation.’ Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Low risk	‘The principle investigator, study physicians, study coordinator, and assessment staff were all blinded to the patients’ treatment condition throughout the trial. Patients were asked not to divulge what treatment they were receiving to the study physician.’ Comment: Probably done
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is described, no significant descriptions between completers and non-completers were reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Kroener-Herwig 2002

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, six months
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Kroener-Herwig 2002

Participants	<p>End of treatment n = 75</p> <p>Start of treatment n = 78</p> <p>Sex: 35F, 40M</p> <p>Mean age = 12.1 (sd 1.3)</p> <p>Source = Newspaper advertisement - two or more headaches per month reported by parents</p> <p>Diagnosis = Paediatric headache: migraine (30%), tension-type (40%), combined (30%)</p> <p>Mean years of pain = 4.0 (sd 2.6)</p>
Interventions	<p>“Cognitive behavioural training group”</p> <p>“Self-help”</p> <p>“Waiting list control”</p>
Outcomes	<p>Primary Pain Outcome: pain intensity</p> <p>Primary Disability Outcome: none</p> <p>Primary Mood Outcome: none</p> <p>1. Headache frequency (mean no. per day)</p> <p>2. Pain intensity (mean daily)</p> <p>3. Headache duration (mean no hours per day)</p>
Notes	<p>Updated Study 2012</p> <p>Total Quality = 19/35</p> <p>Treatment Quality = 7/9</p> <p>Design Quality = 12/26</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Assignment to the treatment groups was random.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant descriptions between completers and non-completers was not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Labbe 1984

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment (one month after end of treatment), six months
Participants	<p>End of treatment n = 28</p> <p>Start of Treatment n = 28</p>

Labbe 1984

	Sex: 14F, 14M Mean age = 10.8 Source = Community paediatrician referral, newspaper advertisement Diagnosis = Migraine headache Mean years of pain = 4.3
Interventions	“Autogenic feedback training” “Waiting list control”
Outcomes	Primary Pain Outcome: Headache diary Primary Disability Outcome: none Primary Mood Outcome: none 1. Headache index 2. Headache frequency 3. Headache duration 4. Headache peak intensity 5. Medication use
Notes	Original Study Total Quality = 16/35 Treatment Quality = 4/9 Design Quality = 12/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The children who attended the first session were matched on age, sex, and baseline headache index and then randomly assigned to either a treatment group or waiting-list control group.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts reported in study.
Selective reporting (reporting bias)	Low risk	Data were reported fully.

Labbe 1995

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, six months
Participants	End of treatment n = 30 Start of Treatment n = 46 Sex: 17F, 13M

Labbe 1995

	Mean age =12.0 Source = Not given Diagnosis = Vascular or migraine headache Mean years of pain = not given.
Interventions	“Skin temperature biofeedback and autogenic relaxation” “Autogenic relaxation” “Waiting list control”
Outcomes	Primary Pain Outcome: headache diary Primary Disability Outcome: none Primary Mood Outcome: Childhood Depression Inventory 1. Headache index 2. Headache frequency 3. Headache duration 4. Child aggression parent-rated (Myth Type A) 5. Childhood Depression Inventory 6. How-I-Feel questionnaire: anxiety
Notes	Original Study Total Quality = 11/35 Treatment Quality = 2/9 Design Quality = 9/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Children were matched by age, sex, and baseline headache activity and then randomly assigned to one of three groups.' Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	'Data on the dropouts were compared to those children participating in the treatment sessions. No differences were found in sex, age or headache history.' Comment: Probably done
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Larsson 1987a

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, five months
Participants	End of treatment n = 46

Larsson 1987a

	Start of Treatment n = 46 Sex: 40F, 6M Mean age = Not given: range 16–18 Source = Not given Diagnosis = Headache (migraine, tension, or both) Mean years of pain = Most one-five years
Interventions	“Therapist assisted relaxation” “Self-help relaxation” “Self monitoring group”
Outcomes	Primary Pain Outcome: Headache sum Primary Disability Outcome: school absence Primary Mood Outcome: none 1. Headache sum 2. Headache frequency 3. Headache-free days 4. Headache duration 5. Peak headache intensity 6. Medication 7. School absence 8. Significant other rating of headache improvement 9. Cost-effectiveness
Notes	Original Study Total Quality = 21/35 Treatment Quality = 6/9 Design Quality = 15/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'In the randomisation procedure'. Comment: Probably done, no method described
Allocation concealment (selection bias)	High risk	'In the randomisation procedure the following restrictions were applied: (a) class mates were assigned to the same treatment group in order to lessen the risk of treatment contamination, (b) subjects were evenly distributed across groups within separate schools.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers were not reported
Selective reporting (reporting bias)	High risk	Data were not fully reported.

Larsson 1987b

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, five months
Participants	End of treatment n = 36, follow-up n = 34 Start of Treatment n = 36 Sex: 32F, 2M Mean age = 17 Source = Not given Diagnosis = Headache Mean years of pain = Most 1–5 years
Interventions	“Self-help relaxation” “Problem discussion group” “Self monitoring (control)”
Outcomes	Primary Pain Outcome: Headache sum Primary Disability Outcome: School absence Primary Mood Outcome: Depression 1. Headache sum 2. Headache frequency 3. Headache-free days 4. Headache duration 5. Peak headache intensity 6. Medicine consumption 7. School absence 8. Headache annoyance 9. Depression/anxiety 10. Social relationship-competence questionnaire 11. Significant other rating of headache improvement
Notes	Original Study Total Quality = 16/35 Treatment Quality = 5/9 Design Quality = 11/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Finally, 36 students were randomly assigned to the three experimental conditions.' Comment: Probably done, no method described
Allocation concealment (selection bias)	High risk	'The allocation of subjects was conducted with two restrictions on the procedure: (a) Classmates were assigned to the same treatment condition (to lessen the risk of treatment contamination), and (b) students with a high frequency of headaches were identified and evenly distributed across groups.' Comment: Probably done

Larsson 1987b

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition is not described.
Selective reporting (reporting bias)	High risk	Data were not fully reported.

Larsson 1990

Methods	RCT Two arms. Assessed at pre-treatment, post-treatment
Participants	End of treatment n = 43 Start of Treatment n = 49 Sex: 44F, 5M Mean age =17 Source = School Diagnosis = Headache Mean years of pain = median 2–5 years
Interventions	“Self help relaxation” “Waiting list control”
Outcomes	Primary Pain Outcome: Headache activity Primary Disability Outcome: none given Primary Mood Outcome: Depression (BDI) 1. Headache index 2. Medication use 3. Headache annoyance 4. Modified Child Manifest Anxiety Scale (CMAS) 5. Depression - Beck Depression Inventory 6. Somatic complaints (composite of multiple complaints) 7. Stress (4-point scale)
Notes	Original Study Total Quality = 12/35 Treatment Quality = 4/9 Design Quality = 8/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'...the outlines of the study including the use of randomisation and a placebo treatment period.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias)	Unclear risk	'A graduate student in psychology admin-

Larsson 1990

bias) All outcomes		istered the assessment instruments and the treatment material used in the study.' Comment: unsure
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant descriptions between completers and non-completers was not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Larsson 1996

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, six months	
Participants	End of treatment n = 26 Start of Treatment n = 26 Sex: 25F, 1M Mean age = Not given: range 10–15 years Source = School Diagnosis = Headache Mean years of pain =2.1	
Interventions	"Relaxation treatment" "No treatment"	
Outcomes	Primary Pain Outcome: Headache intensity Primary Disability Outcome: None Primary Mood Outcome: None 1. Headache intensity ('sum') 2. Headache-free days 3. Headache frequency	
Notes	Original Study Total Quality = 20/35 Treatment Quality = 6/9 Design Quality = 14/26	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Thus, 26 pupils were randomly allocated into a relaxation training group or to a no-treatment control group'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no dropouts reported in the study.

Larsson 1996

Selective reporting (reporting bias)	Low risk	Data were fully reported.
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Levy 2010

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, three-month follow-up, six-month follow-up	
Participants	<p>End of treatment n = 168, Follow-up three months n = 143, Follow-up six months = 154</p> <p>Start of treatment n = 200</p> <p>Sex: 145F, 55M</p> <p>Mean age = 11.21 (2.55)</p> <p>Source = Pediatric gastroenterology clinics at Seattle Children's Hospital and the Atlantic Health System in Morristown, New Jersey. Seattle participants were also recruited through local area clinics and community-posted flyers</p> <p>Diagnosis = Functional Abdominal Pain</p> <p>Mean years of pain = 3+ episodes of abdominal pain during a 3-month period</p>	
Interventions	<p>"Cognitive-behavioural treatment"</p> <p>"Educational intervention"</p>	
Outcomes	<p>Primary Pain Outcome: Faces Pain Scale-Revised</p> <p>Primary Disability Outcome: Functional Disability Inventory</p> <p>Primary Mood Outcome: Children's Depression Inventory</p> <ol style="list-style-type: none"> 1. Faces Pain Scale-Revised 2. Functional Disability Inventory 3. Children's Depression Inventory 4. Children's Somatization Inventory 5. Multidimensional Anxiety Scale for Children 	
Notes	<p>Updated study 2012</p> <p>Total Quality = 27/35</p> <p>Treatment Quality = 7/9</p> <p>Design Quality = 20/26</p>	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomisation was then performed by a different researcher using a computerised random-number generator, stratifying by age.' Comment: probably done
Allocation concealment (selection bias)	Low risk	'Randomisation was then performed by a different researcher using a computerised random-number generator, stratifying by age.' Comment: probably done
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Nurse assessors were blind to the treatment assignment of the children.' Comment: Probably done
Incomplete outcome data (attrition bias)	Unclear risk	Attrition is described, significant differ-

Levy 2010

All outcomes		ences between completers and non-completers are not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

McGrath 1988

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, three months, 12 months	
Participants	End of treatment n = 99 Start of Treatment n =136 Sex: 69F, 30M Mean age =13.1 (range 11–18) source = Hospital Diagnosis = Headache Mean years of pain = not given: minimum three months	
Interventions	“Relaxation training” “Attention control” “Own best efforts”	
Outcomes	Primary Pain Outcome: Headache index Primary Disability Outcome: none Primary Mood Outcome: none 1. Headache index 2. Headache-free days 3. Highest pain intensity	
Notes	Original Study Total Quality = 23/35 Treatment Quality = 7/9 Design Quality = 16/26	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomly assigned to one of three groups'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is described, however significant differences between completers and non-completers are not reported
Selective reporting (reporting bias)	Low risk	Data were completely reported.

McGrath 1992

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, three months and one-year follow-up
Participants	End of treatment n = 74 Start of Treatment n = 87 Sex: 63F, 24M Mean age = Not given: range 11–18 years Source = Paediatricians and family physicians Diagnosis = Migraine Mean years of pain not given: minimum three months
Interventions	“Therapist administered cognitive behavioural/stress coping/ relaxation training” “Self-administered cognitive behavioural/ stress coping/ relaxation training” “Information and support”
Outcomes	Primary Pain Outcome: Headache diary Primary Disability Outcome: None Primary Mood Outcome: Depression 1. Headache index 2. Efficiency of treatment 3. Poznanski Depression Scale
Notes	Original Study Total Quality = 15/35 Treatment Quality = 2/9 Design Quality = 13/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomised to 1 of the 8-week treatments'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers are not reported
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Osterhaus 1997

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment and one-year follow-up
Participants	End of treatment n = 39, one-year follow-up n = 21.

Osterhaus 1997

	Start of Treatment n = 39 Sex: 29F, 10M Mean age = 15.2 (sd 3.3) Source = Newspaper article Diagnosis = Headache (migraine, tension-type, mixed) Mean years of pain = 5.6
Interventions	"Behavioural treatment package" "Waiting list control"
Outcomes	Primary Pain Outcome: Headache index Primary Disability Outcome: none Primary Mood Outcome: none 1. Headache index 2. Headache frequency 3. Headache duration 4. Headache intensity
Notes	Original Study Total Quality = 18/35 Treatment Quality = 6/9 Design Quality = 12/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The participants were randomly assigned to one of two groups'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition is not described.
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Palermo 2009

Methods	RCT. Two arms. Assessed at pre-treatment and post-treatment.
Participants	End of treatment n = 44 Start of treatment n = 48 Sex: 35F, 13M Mean age = 14.8 (2.0) Source = Medical centre in the Pacific Northwest USA

Palermo 2009

	Diagnosis = Headache (25% of the sample), abdominal pain (50% of the sample), or musculoskeletal pain (25% of the sample) Mean years of pain = 30 months
Interventions	“Internet-delivered family cognitive-behavioural therapy” “Wait-list control group”
Outcomes	Primary Pain Outcome: Daily Pain Intensity NRS (averaged over seven days) Primary Disability Outcome: Child Activity and Limitations Interview Primary Mood Outcome: Revised Child Anxiety and Depression Scale 1. Daily pain intensity NRS (averaged over seven days) 2. Usual pain intensity over the past month NRS 2. Child Activity Limitations Interview 3. Revised Child Anxiety and Depression Scale 4. Protect sub scale from Adult Responses to Children's Symptoms 5. Treatment acceptability and satisfaction
Notes	Updated Study 2012 Total Quality = 30/35 Treatment Quality = 8/9 Design Quality = 22/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'A fixed allocation randomisation scheme was used. Specifically, we used blocked randomisation with blocks of 10 to assign participants to the two treatment conditions during the course of randomisation. An online random number generator was used to produce the blocked randomisation. Group assignments were identified by ID number in sealed envelopes. Following completion of all pre-treatment assessments, a research coordinator opened the sealed envelope to reveal the group assignment.' Comment: probably done
Allocation concealment (selection bias)	Low risk	'A fixed allocation randomisation scheme was used. Specifically, we used blocked randomisation with blocks of 10 to assign participants to the two treatment conditions during the course of randomisation. An online random number generator was used to produce the blocked randomisation. Group assignments were identified by ID number in sealed envelopes. Following completion of all pre-treatment assessments, a research coordinator opened the sealed envelope to reveal the group assignment.' Comment: probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias)	Unclear risk	Attrition is described, however significant differences between completers and non-

Palermo 2009

All outcomes		completers were not described
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Selective reporting (reporting bias)	Low risk	Data were fully reported.
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Passchier 1990

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment.	
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Participants	End of treatment n = 119 Start of Treatment n = 119 Sex: 65F, 54M Mean age = 13.7 (sd 1.4) Source = School Diagnosis = Headache (at least weekly) Mean years of pain = None given	
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Interventions	"Progressive relaxation training" "Placebo physical concentration training"	
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Outcomes	Primary Pain Outcome: Headache intensity Primary Disability Outcome: School problems Primary Mood Outcome: Anxiety (Fear of Failure) 1. Headache intensity 2. Headache frequency 3. Headache duration 4. School problems (composite) 5. Fear of failure (from Hermans Debilitating Anxiety of Achievement Motivation Test)	
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Notes	Original Study Total Quality = 15/35 Treatment Quality = 5/9 Design Quality = 10/26	
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The 19 classes of the participating teachers were allocated at random to a Progressive Relaxation Training or a Placebo Training group.' Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported.
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Richter 1986

Methods	RCT. Three arms. Assessed at pre-treatment, posttreatment
Participants	End of treatment n = 43 Start of Treatment n = 51 Sex: 34F, 17M Mean age = 12.9 Source = Referred by physicians to children's hospital Diagnosis = Migraine Mean years of pain = Not given: most over two years
Interventions	"Relaxation training" "Cognitive coping" "Attention control"
Outcomes	Primary Pain Outcome: Headache diary Primary Disability Outcome: None Primary Mood Outcome: Child Depression rating scale 1. Headache index (intensity, frequency, duration, medication taken: diary) 2. State Trait Anxiety Inventory (STAI) <i>or</i> State-Trait Anxiety Inventory for Children (STAI-C) 3. Children's Depression Rating Scale
Notes	Original Study Total Quality = 20/35 Treatment Quality = 6/9 Design Quality = 14/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'And randomly assigned to treatment'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	'Over the course of treatment there were 8 drop-outs. A chi-square analysis comparing attrition rates across interventions was not significant.' Comment: Attrition adequately reported and no significant differences between completers and non-completers reported
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Robins 2005

Robins 2005

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment (three months after start), six to twelve months
Participants	End of treatment n = 69 Start of treatment n = 86 Sex: 39F, 30M Mean age = 11.4 (sd 2.4) Source = Paediatric gastroenterology outpatient clinic of children's hospital Diagnosis = Recurrent abdominal pain Mean years of pain = Not stated
Interventions	"Short term cognitive behavioural family treatment plus standard medical care" "Standard medical care"
Outcomes	Primary Pain Outcome: Abdominal Pain Index Primary Disability Outcome: Functional Disability Inventory Primary Mood Outcome: none 1. Abdominal Pain Index 2. Child Somatization Inventory 3. Functional Disability Inventory 4. Abdominal Pain Index (parent) 5. Child Somatization Inventory (parent)
Notes	Updated Study 2009 Total Quality = 27/35 Treatment Quality = 7/9 Design Quality = 20/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'The remaining sample of 86 were randomly assigned using a coin-flip method.' Comment: Probably done
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers were not described
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Sanders 1994

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, six months, one year
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Sanders 1994

Participants	End of treatment n = 44 Start of Treatment n = 44 Sex: 28F, 16M Mean age = 9.2 (sd 1.9) Source = Not given Diagnosis = Recurrent abdominal pain Mean years of pain = 3.7
Interventions	"Cognitive behaviour therapy" "Standard paediatric care"
Outcomes	Primary Pain Outcome: pain diary Primary Disability Outcome: Interference with child activity Primary Mood Outcome: none 1. Pain intensity diary 2. Parent observation of child pain behaviour (POR) 3. Child behaviour checklist (CBCL '83) 4. Relapse vs pain-free 5. Interference with child activity (child report) 6. Interference with child activity (parent report)
Notes	Original Study Total Quality = 19/35 Treatment Quality = 4/9 Design Quality = 15/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The study used a randomised group comparison design with two treatment conditions.' Comment: method not described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was not described and significant differences between completers and non-completers were not reported
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Sartory 1998

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment (four weeks after end of intervention), eight months follow-up
Participants	End of treatment n = 43

Sartory 1998

	Start of Treatment n = 43 Sex: 17F, 26M Mean age = 11.3 (sd 2.1) source = Outpatient clinic of paediatric hospital and advertising in press Diagnosis = Migraine Mean years of pain = 4.6
Interventions	"Cephalic vasomotor training + stress management" "Relaxation training + stress management" "Beta-blocker (metoprolol)"
Outcomes	Primary Pain Outcome: headache index Primary Disability Outcome: none Primary Mood Outcome: mood faces scale 1. Headache index 2. Episodes/week when analgesics taken 3. Mood faces scale, 5-point smiling - upset
Notes	Updated Study 2009 Total Quality = 19/35 Treatment Quality = 6/9 Design Quality = 13/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Children were allocated randomly to one of three treatment groups'. Comment: Probably done, no method described
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers were not described
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Scharff 2002

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, three months, six months, twelve months
Participants	End of treatment n = 34 Start of Treatment n = 36 Sex: 24F, 12M Mean age 12.8 (sd 2.4)

Scharff 2002

	Source = Children's hospital Diagnosis = Migraine (all), tension-type headache (minority) Mean years of pain = 2.4 (sd 2.1)
Interventions	"Handwarming biofeedback and stress management" "Handcooling attention control" "Waitlist control"
Outcomes	Primary Pain Outcome: headache index Primary Disability Outcome: none Primary Mood Outcome: Child Depression Inventory 1. Headache index 2. Days with headache 3. Highest headache rating 4. Child Depression Inventory (CDI) 5. Stait-Trait Anxiety Inventory for Children (STAIC)
Notes	Updated Study 2009 Total Quality = 19/35 Treatment Quality = 4/9 Design Quality = 15/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'At the assessment visit children were randomised into three groups using a randomisation table'. Comment: probably done
Allocation concealment (selection bias)	Unclear risk	No description found in text. Comment: Probably not done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is described, there were no significant differences between completers and non-completers
Selective reporting (reporting bias)	High risk	Data were incompletely reported.

Stinson 2010

Methods	RCT. Two arms. Assessed at pre-treatment and post-treatment
Participants	End of treatment n = 39 Start of treatment n = 46 Sex: 31F, 15M Mean age = 14.6 (sd 1.5) Source = Four paediatric tertiary care centres

Stinson 2010

	Diagnosis = Juvenile Idiopathic Arthritis Mean years of pain = 6.4 (sd 4.6)
Interventions	“Internet treatment” “Attentional control group”
Outcomes	Primary Pain Outcome: Recall Pain Inventory Primary Disability Outcome: Juvenile Arthritis Quality of Life Questionnaire Primary Mood Outcome: Perceived Severity of Stress Questionnaire 1. Recall Pain Inventory 2. Juvenile Arthritis Quality of Life Questionnaire 3. Perceived Severity of Stress Questionnaire 4. Medical Issues, Exercise, Pain and Social Support Questionnaire 5. Children’s Arthritis Self-Efficacy scale 6. JIA-specific Child Adherence Report Questionnaire 7. Parent Adherence Report Questionnaire
Notes	Updated study 2012 Total Quality = 30/35 Treatment Quality = 9/9 Design Quality = 21/26

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	‘A fixed allocation randomisation scheme was used. Specifically, blocked randomisation was employed. An online random number generator was used to produce the blocked randomisation. Group assignments were identified by ID number in sealed envelopes during the recruitment period.’ Comment: Probably done
Allocation concealment (selection bias)	Low risk	‘A fixed allocation randomisation scheme was used. Specifically, blocked randomisation was employed. An online random number generator was used to produce the blocked randomisation. Group assignments were identified by ID number in sealed envelopes during the recruitment period.’ Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is reported. However, significant differences between completers and non-completers were not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Trautmann 2010

Methods	RCT. Three arms. Assessed at pre-treatment, post-treatment, six months
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Trautmann 2010

Participants	<p>End of treatment n = 55, Follow-up n = 40</p> <p>Start of treatment n = 68</p> <p>Sex: 36F, 30M</p> <p>Mean age = 12.7 (sd 2.2)</p> <p>Source = Newspaper adverts and websites</p> <p>Diagnosis = Headache (migraine, tension type headache or combined headache)</p> <p>Mean years of pain = 2.8 (sd 3.0)</p>
Interventions	<p>“Cognitive behavioural therapy, self-help and management”</p> <p>“Applied relaxation group”</p> <p>“Education”</p>
Outcomes	<p>Primary Pain Outcome: Pain Diary</p> <p>Primary Disability Outcome: none</p> <p>Primary Mood Outcome: Children’s Depression Inventory</p> <ol style="list-style-type: none"> 1. Pain diary 2. Children’s depression inventory 3. Pain Catastrophising scale 4. Health-related quality of life (KINDL-R) 5. Strength and difficulties questionnaire
Notes	<p>Updated study 2012</p> <p>Total Quality = 29/35</p> <p>Treatment Quality = 8/9</p> <p>Design Quality = 21/26</p>

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	‘All participants were randomly assigned to one of the three conditions. The randomly ordered list of groups was used to assign sequentially enrolled participants to two intervention groups and the active control condition.’ Comment: Probably done
Allocation concealment (selection bias)	Low risk	‘The first author randomly selected participants according to a computer-generated randomisation list by using the ‘select cases’ random selection option.’ Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is described. ‘Furthermore, no significant differences were found between dropouts and completers’
Selective reporting (reporting bias)	Low risk	Data were fully extracted.

van Tilburg 2009

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, six months
Participants	End of treatment n = 29, Follow-up n = 24 Start of treatment n = 34 Sex: 25F, 9M Mean age = 10.25 (sd 2.6) Source = University of North Carolina and Duke University Medical Centres Diagnosis = Functional abdominal pain Mean years of pain = unknown
Interventions	“Guided imagery treatment” “Standard medical care”
Outcomes	Primary Pain Outcome: Abdominal Pain Index Primary Disability Outcome: Functional Disability Inventory Primary Mood Outcome: none 1. Abdominal pain index 2. Functional disability inventory 3. School attendance 4. Pediatric quality of life inventory 5. Global rating of change in abdominal pain 6. Treatment compliance 7. Questionnaire of paediatric gastrointestinal symptoms 8. Health care utilisation
Notes	Updated study 2012 Total Quality = 21/35 Treatment Quality = 8/9 Design Quality = 13/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Thirty-four children, were assigned randomly to receive 2 months of standard medical care with or without home-based, guided imagery treatment.' Comment: Probably done, method not described
Allocation concealment (selection bias)	Low risk	'Children picked a closed envelope that determined whether they would receive standard medical care with or without guided imagery treatment.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No description found in text. Comment: Probably not done.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers are not reported

van Tilburg 2009

Selective reporting (reporting bias)	Low risk	Data were fully reported.
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Vlieger 2007

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, six months, one year
Participants	End of treatment n = 51 Start of Treatment n = 52 Sex: 39F, 13M Mean age = 13.3 (sd 2.7) Source = Paediatric gastroenterology dept in hospital Diagnosis = Functional abdominal pain (N = 31) and irritable bowel syndrome (IBS) (N = 22) Mean years of pain = 3.4
Interventions	“Gut-directed hypnotherapy” “Standard medical care plus supportive therapy”
Outcomes	Primary Pain Outcome: weekly pain intensity Primary Disability Outcome: none Primary Mood Outcome: none 1. Total pain intensity over 1 week (9-point faces affective pain intensity scale, reduced to 0–3 points hence 0–21) 2. Total pain frequency over 1 week (frequency reduced to 0–3 scale per day) 3. Associated symptoms (nausea, vomiting, loss of appetite, flatus, nocturnal pain, pain on wakening, pain related to meals)
Notes	Updated Study 2009 Total Quality = 24/35 Treatment Quality = 6/9 Design Quality = 18/26

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Patients were randomly allocated using a computerised random-number generator for concealment to either HT or standard medical care.' Comment: Probably done
Allocation concealment (selection bias)	Low risk	'Patients were randomly allocated using a computerised random-number generator for concealment to either HT or standard medical care.' Comment: Probably done
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Pain diaries were analysed by S. W. (medical student), who was blinded to the treatment arm.' Comment: Probably done
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers are not reported
Selective reporting (reporting bias)	Low risk	Data were fully reported.

Wicksell 2009

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, 3.5 months, 6.8 months
Participants	<p>End of treatment n = 29, Follow-up 3.5 months n = 24, Follow-up 6.8 months = 24</p> <p>Start of treatment n = 32</p> <p>Sex: 25F, 7M</p> <p>Mean age = 14.8 (sd 2.4)</p> <p>Source = Astrid Lindgren Children's Hospital, Karolinska University Hospital</p> <p>Diagnosis = Mixed pain (headache, back/neck, widespread musculoskeletal, complex regional pain syndrome, visceral, lower extremities, postherpetic type cheek pain)</p> <p>Mean years of pain = 2.7</p>
Interventions	<p>"Exposure and acceptance"</p> <p>"Multidisciplinary treatment and amitriptyline"</p>
Outcomes	<p>Primary Pain Outcome: Pain Intensity</p> <p>Primary Disability Outcome: Functional Disability Inventory</p> <p>Primary Mood Outcome: Center for Epidemiological Studies Depression Scale for Children</p> <ol style="list-style-type: none"> 1. Pain intensity 2. Functional disability inventory 3. Center for Epidemiological Studies Depression Scale for Children 4. Multidimensional Pain Inventory (interference scale) 5. Brief pain inventory (pain interference items) 6. Pain and impairment relationship scale 7. Short form-36 health survey 8. Tampa scale of Kinesiophobia 9. Pain coping questionnaire (internalising and catastrophising) 10. 5 author-generated questions on pain-related discomfort
Notes	<p>Updated study 2012</p> <p>Total Quality = 20/35</p> <p>Treatment Quality = 6/9</p> <p>Design Quality = 14/26</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'A total of 32 participants were included in the study and randomised to one of the two treatment conditions. A simple randomisation technique was used.' Comment: Probably done
Allocation concealment (selection bias)	Low risk	'A sealed envelope (prepared by a secretary blind to the objective of the study) containing a code for 'exposure and acceptance' or 'MDT' was opened, assigning the participant to one of the treatment conditions.' Comment: probably done
Blinding of outcome assessment (detection bias)	Low risk	'All assessments were conducted by a nurse who was not involved in delivering the

Wicksell 2009

All outcomes		treatment protocol.' Comment: Probably done
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition is described, however significant differences between completers and non-completers are not reported
Selective reporting (reporting bias)	Low risk	Data are fully reported.

CBT: Cognitive behavioural therapy
 FDI-C: Functional Disability Inventory-Children
 JPFM: Juvenile Primary Fibromyalgia
 NRS: Numeric rating scale
 PEDSQL: Paediatric Scale Quality of Life Inventory
 RCT: Randomised controlled trial
 SCD: Sickle cell disease
 VAS: Visual analogue scale

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Fentress 1986	Inadequate sample size ($n < 10$ in one arm of study design)
Kroener-Herwig 1998	Inadequate sample size ($n < 10$ in one arm of study design)
Larsson 1986	Inadequate sample size ($n < 10$ in one arm of study design)
Olness 1987	Insufficient psychological treatment
Sanders 1989	Inadequate sample size ($n < 10$ in one arm of study design)
Trautmann 2008	Inadequate sample size ($n < 10$ in one arm of study design)
Vlieger 2012	Follow-up period more than one year
Weydert 2006	Inadequate sample size ($n < 10$ in one arm of study design)
Youssef 2009	Inadequate sample size ($n < 10$ in one arm of study design)