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# Psychological therapies for the management of chronic pain (excluding headache) in adults (Review)

Williams ACDC, Fisher E, Hearn L, Eccleston C

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# [Intervention Review]

# Psychological therapies for the management of chronic pain (excluding headache) in adults

Amanda C de C Williams<sup>1</sup>, Emma Fisher<sup>2,3</sup>, Leslie Hearn<sup>4</sup>, Christopher Eccleston<sup>3</sup>

<sup>1</sup>Research Department of Clinical, Educational & Health Psychology, University College London, London, UK. <sup>2</sup>Cochrane Pain, Palliative and Supportive Care Group, Pain Research Unit, Churchill Hospital, Oxford, UK. <sup>3</sup>Centre for Pain Research, University of Bath, Bath, UK. <sup>4</sup>Cochrane Pain, Palliative and Supportive Care Group, Pain Research Unit, Churchill Hospital, Oxford, UK

Contact address: Amanda C de C Williams, amanda.williams@ucl.ac.uk, ucjtamw@ucl.ac.uk.

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# ABSTRACT

#### Background

Chronic non-cancer pain, a disabling and distressing condition, is common in adults. It is a global public health problem and economic burden on health and social care systems and on people with chronic pain. Psychological treatments aim to reduce pain, disability and distress. This review updates and extends its previous version, published in 2012.

# Objectives

To determine the clinical efficacy and safety of psychological interventions for chronic pain in adults (age  $\geq$  18 years) compared with active controls, or waiting list/treatment as usual (TAU).

# Search methods

We identified randomised controlled trials (RCTs) of psychological therapies by searching CENTRAL, MEDLINE, Embase and PsycINFO to 16 April 2020. We also examined reference lists and trial registries, and searched for studies citing retrieved trials.

#### **Selection criteria**

RCTs of psychological treatments compared with active control or TAU of face-to-face therapies for adults with chronic pain. We excluded studies of headache or malignant disease, and those with fewer than 20 participants in any arm at treatment end.

#### Data collection and analysis

Two or more authors rated risk of bias, extracted data, and judged quality of evidence (GRADE). We compared cognitive behavioural therapy (CBT), behavioural therapy (BT), and acceptance and commitment therapy (ACT) with active control or TAU at treatment end, and at six month to 12 month follow-up. We did not analyse the few trials of other psychological treatments. We assessed treatment effectiveness for pain intensity, disability, and distress. We extracted data on adverse events (AEs) associated with treatment.

# **Main results**

We added 41 studies (6255 participants) to 34 of the previous review's 42 studies, and now have 75 studies in total (9401 participants at treatment end). Most participants had fibromyalgia, chronic low back pain, rheumatoid arthritis, or mixed chronic pain. Most risk of bias domains were at high or unclear risk of bias, with selective reporting and treatment expectations mostly at unclear risk of bias. AEs were inadequately recorded and/or reported across studies.

# СВТ

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The largest evidence base was for CBT (59 studies). CBT versus active control showed very small benefit at treatment end for pain (standardised mean difference (SMD) -0.09, 95% confidence interval (CI) -0.17 to -0.01; 3235 participants; 23 studies; moderate-quality evidence), disability (SMD -0.12, 95% CI -0.20 to -0.04; 2543 participants; 19 studies; moderate-quality evidence), and distress (SMD -0.09, 95% CI -0.18 to -0.00; 3297 participants; 24 studies; moderate-quality evidence). We found small benefits for CBT over TAU at treatment end for pain (SMD -0.22, 95% CI -0.33 to -0.10; 2572 participants; 29 studies; moderate-quality evidence), disability (SMD -0.32, 95% CI -0.45 to -0.19; 2524 participants; 28 studies; low-quality evidence), and distress (SMD -0.34, 95% CI -0.44 to -0.24; 2559 participants; 27 studies; moderate-quality evidence). Effects were largely maintained at follow-up for CBT versus TAU, but not for CBT versus active control.

Evidence quality for CBT outcomes ranged from moderate to low. We rated evidence for AEs as very low quality for both comparisons.

# BT

We analysed eight studies (647 participants). We found no evidence of difference between BT and active control at treatment end (pain SMD -0.67, 95% CI -2.54 to 1.20, very low-quality evidence; disability SMD -0.65, 95% CI -1.85 to 0.54, very low-quality evidence; or distress SMD -0.73, 95% CI -1.47 to 0.01, very low-quality evidence). At follow-up, effects were similar. We found no evidence of difference between BT and TAU (pain SMD -0.08, 95% CI -0.33 to 0.17, low-quality evidence; disability SMD -0.02, 95% CI -0.24 to 0.19, moderate-quality evidence; distress SMD 0.22, 95% CI -0.10 to 0.54, low-quality evidence) at treatment end. At follow-up, we found one to three studies with no evidence of difference between BT and TAU.

We rated evidence for all BT versus active control outcomes as very low quality; for BT versus TAU. Evidence quality ranged from moderate to very low. We rated evidence for AEs as very low quality for BT versus active control. No studies of BT versus TAU reported AEs.

# ACT

We analysed five studies (443 participants). There was no evidence of difference between ACT and active control for pain (SMD -0.54, 95% CI -1.20 to 0.11, very low-quality evidence), disability (SMD -1.51, 95% CI -3.05 to 0.03, very low-quality evidence) or distress (SMD -0.61, 95% CI -1.30 to 0.07, very low-quality evidence) at treatment end. At follow-up, there was no evidence of effect for pain or distress (both very low-quality evidence), but two studies showed a large benefit for reducing disability (SMD -2.56, 95% CI -4.22 to -0.89, very low-quality evidence). Two studies compared ACT to TAU at treatment end. Results should be interpreted with caution. We found large benefits of ACT for pain (SMD -0.83, 95% CI -1.57 to -0.09, very low-quality evidence), but none for disability (SMD -1.39, 95% CI -3.20 to 0.41, very low-quality evidence), or distress (SMD -1.16, 95% CI -2.51 to 0.20, very low-quality evidence). Lack of data precluded analysis at follow-up.

We rated evidence quality for AEs to be very low. We encourage caution when interpreting very low-quality evidence because the estimates are uncertain and could be easily overturned.

# **Authors' conclusions**

We found sufficient evidence across a large evidence base (59 studies, over 5000 participants) that CBT has small or very small beneficial effects for reducing pain, disability, and distress in chronic pain, but we found insufficient evidence to assess AEs. Quality of evidence for CBT was mostly moderate, except for disability, which we rated as low quality. Further trials may provide more precise estimates of treatment effects, but to inform improvements, research should explore sources of variation in treatment effects. Evidence from trials of BT and ACT was of moderate to very low quality, so we are very uncertain about benefits or lack of benefits of these treatments for adults with chronic pain; other treatments were not analysed. These conclusions are similar to our 2012 review, apart from the separate analysis of ACT.

# PLAIN LANGUAGE SUMMARY

# What are the benefits and risks of psychological therapies for adults with persistent and distressing pain that is neither cancerrelated nor a headache?

### Why this question is important

Many people experience pain that lasts more than three months that is neither cancer-related nor a headache. The search for a diagnosis and pain relief is often long and can be discouraging. For some, persistent pain leads to disability, depression, anxiety and social isolation.

Psychological treatments (talking and behaviour therapies) aim to help people change the way they manage pain, to minimise disability and distress. To find out how effective these treatments are when delivered by a trained psychologist, and whether they cause any unwanted (adverse) effects, we reviewed the research evidence.

# How we identified and assessed the evidence

First, we searched for all relevant studies in the medical literature. We then compared the results, and summarised the evidence from all the studies. Finally, we assessed the quality of the evidence. We considered factors such as the way studies were conducted, study sizes, and consistency of findings across studies. Based on our assessments, we rated the evidence as being of very low, low, moderate or high certain quality.



#### What we found

We found 75 studies that included 9401 people with a range of chronic pain conditions, including fibromyalgia, chronic low back pain, rheumatoid arthritis, and a mixture of persistent pain conditions. The average age of participants was 50, and the average duration of their pain was nine years. In the studies, people were followed for up to three years after the end of their treatment.

Studies evaluated the following psychological treatments: cognitive behavioural therapy (CBT, 59 studies), behavioural therapy (BT, eight studies), acceptance and commitment therapy (ACT, five studies) or another psychological therapy (six studies). We report the findings for the main treatment that was evaluated, CBT. CBT focuses on changing the way someone thinks and behaves, to help them manage their symptoms better. Results are averages for the whole population studied: individuals within the population may change more or less than the average.

#### The evidence suggests that:

- On average, compared to people who receive no treatment for their pain, people treated with CBT probably experience slightly less pain and distress by the end of the treatment and six to 12 months later (moderate-quality evidence). They may also experience slightly less disability on average (low-quality evidence).

- On average, compared to people who receive a non-psychological treatment for their pain (such as an exercise programme, or education about managing pain), people treated with CBT probably experience very slightly less pain, disability and distress by the end of the treatment (moderate-quality evidence). On average, six to 12 months later, they probably experience very slightly less pain and distress (moderate-quality evidence), but levels of disability may be similar to those of people who received a non-psychological treatment (low-quality evidence).

We do not know if CBT causes more, fewer or similar numbers of adverse effects than no treatment or another treatment, because the evidence is of very low quality.

#### What this means

CBT has the largest evidence base of all the psychological therapies for persistent pain that we reviewed. The evidence indicates that :

- On average, when compared to no treatment or a non-psychological treatment, CBT probably reduces pain and distress by small or very small amounts;

- On average, compared to no treatment, CBT may reduce levels of disability at the end of the treatment by a small amount. Compared to a non-psychological treatment, CBT probably reduces disability at the end of the treatment by a very small amount on average.

- On average, compared to no treatment, CBT may make a small difference to disability six to 12 months after the treatment. Compared to a non-psychological treatment, however, it may make little to no difference on average.

There is insufficient evidence to draw conclusions about the risks of CBT, and psychological therapies in general, for treating persistent pain.

#### How-up-to date is this review?

The evidence in this Cochrane Review is current to April 2020.



# SUMMARY OF FINDINGS

# Summary of findings 1. Summary of findings: CBT compared with AC for adults with chronic pain

#### CBT compared with AC for adults with chronic pain

Patient or population: Adults with chronic pain (excluding headache)

Settings: Community, primary, secondary, or tertiary care

# Intervention: CBT

Comparison: AC

Outcomes	Probable outcome with No of Par- intervention ticipants (studies)		Quality of Com- the evi- ments dence (GRADE)	
Pain intensity at the end of treatment as measured by multiple scales including VAS, BPI, AIMS, numerical rating scale, MPI	The mean pain intensity in the interven- tion groups was 0.09 SDs lower (95% CI -0.17 to -0.01)	3235 partic- ipants (23 studies)	⊕⊕⊕⊝ moder- ate <sup>a</sup>	
Higher scores indicate higher pain intensity				
Pain intensity at follow-up as measured by multiple scales including VAS, BPI, AIMS, numerical rating scale, MPI	The mean pain intensity in the interven- tion groups was 0.08 SDs lower (95% CI -0.19 to 0.04)	2362 partic- ipants (16 studies)	⊕⊕⊕⊙ moder- ate <sup>a</sup>	
Higher scores indicate higher pain intensity				
Disability at the end of treatment as mea- sured by multiple scales including RMDQ, AIMS	The mean disability in the intervention groups was 0.12 SDs lower (95% CI -0.20 to -0.04)	2543 partic- ipants (19 studies)	⊕⊕⊕⊙ moder- ate <sup>a</sup>	
Higher scores indicate higher levels of disabil- ity				
Disability at follow-up as measured by mul- tiple scales including RMDQ, AIMS	The mean disability in the intervention groups was 0.12 SDs lower (95% CI -0.26 to 0.02)	1919 partic- ipants (15 studies)	⊕⊕⊝⊝ low <sup>a,c</sup>	
Higher scores indicate higher levels of disabil- ity	(0.02)	studiesj		
Distress at the end of treatment as mea- sured by multiple scales including BDI, DASS and CES-D	The mean distress in the intervention groups was 0.09 SDs lower (95% CI -0.18 to -0.00)	3297 partic- ipants (24 studies)	⊕⊕⊕⊙ moder- ate <sup>a</sup>	
Higher scores indicate higher levels of dis- tress				
Distress at follow-up as measured by multi- ple scales including BDI, DASS and CES-D	The mean distress in the intervention groups was 0.13 SDs lower (95% CI -0.25	2363 partic- ipants (16	⊕⊕⊕⊝ moder-	
Higher scores indicate higher levels of dis- tress	to -0.01)	studies)	ate <sup>a</sup>	
<b>Adverse events</b> Higher scores indicate higher numbers of AEs	1 study reported AEs in the control group, 1 study reported AEs in both groups, in- cluding worsening of pain due to therapy, 1 study reported no AEs.	689 partic- ipants (3 studies)	⊕⊙⊙⊙ Could not very combine low <sup>b,d</sup> due to	



lack of data

AC: Active control; AEs: Adverse events; BDI: Beck Depression Inventory; BPI: Brief Pain Inventory; CBT: Cognitive behavioural therapy; CES-D: Centre for Epidemiological Studies - Depression scale; CI: Confidence interval; DASS: Depression Anxiety Stress Scales; MPI: Multidimensional Pain Inventory; RMDQ: Roland-Morris Depression Questionnaire; SDs: Standard deviations; VAS: Visual Analogue Scale.

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.

<sup>a</sup>Downgraded once for serious limitations to study quality <sup>b</sup>Downgraded once for high probability of reporting bias <sup>c</sup>Downgraded once for serious inconsistency <sup>d</sup>Downgraded twice for very serious indirectness

# Summary of findings 2. Summary of findings: CBT compared with TAU for adults with chronic pain

# CBT compared with TAU for adults with chronic pain

Patient or population: Adults with chronic pain (excluding headache)

Settings: Community, primary, secondary, or tertiary care

Intervention: CBT

Comparison: TAU

Outcomes	Probable outcome with intervention	No of Par- ticipants (studies)	Quality of Com- the evi- ments dence (GRADE)
Pain intensity at the end of treatment as measured by multiple scales including VAS, BPI, AIMS, numerical rating scale, MPI Higher scores indicate higher pain intensity	The mean pain intensity in the intervention groups was 0.22 SDs lower (95% CI -0.33 to -0.10)	2572 par- ticipants (29 stud- ies)	⊕⊕⊕⊝ moder- ate <sup>a</sup>
Pain intensity at follow-up as measured by multiple scales including VAS, BPI, AIMS, numerical rating scale, MPI Higher scores indicate higher pain intensity	The mean pain intensity in the intervention groups was 0.16 SDs lower (95% CI -0.27 to -0.04)	1674 par- ticipants (15 stud- ies)	⊕⊕⊕⊝ moder- ate <sup>a</sup>
Disability at the end of treatment as mea- sured by multiple scales including AIMS, ODI, FIQ, MPI Higher scores indicate higher levels of dis- ability	The mean disability in the intervention groups was 0.32 SDs lower (95% CI -0.45 to -0.19)	2524 par- ticipants (28 stud- ies)	⊕⊕⊝⊝ low <sup>a,b</sup>

Disability at follow-up as measured by multiple scales including VAS, BPI, AIMS, numerical rating scale, MPI Higher scores indicate higher levels of dis- ability	The mean disability in the intervention groups was 0.21 SDs lower (95% CI -0.37 to -0.05)	1581 par- ticipants (15 stud- ies)	⊕⊕⊝⊝ Iow <sup>a,b</sup>	
Distress at the end of treatment as mea- sured by multiple scales including BDI, CES-D, SCL-90R, HADS Higher scores indicate higher levels of dis- tress	The mean distress in the intervention groups was 0.34 SDs lower (95% CI -0.44 to -0.24)	2559 par- ticipants (27 stud- ies)	⊕⊕⊕⊙ moder- ate <sup>a</sup>	
Distress at follow-up as measured by mul- tiple scales including BDI, CES-D, SCL-90R, HADS Higher scores indicate higher levels of dis- tress	The mean distress in the intervention groups was 0.25 SDs lower (95% CI -0.37 to -0.13)	1757 par- ticipants (16 stud- ies)	⊕⊕⊕⊝ moder- ate <sup>a</sup>	
<b>Adverse events</b> Higher scores indicate higher numbers of AEs	1 study reported AEs in the control group, 3 studies reported AEs in both groups includ- ing worsening of pain, 1 study reported lack of treatment benefit but no harms, 1 report- ed an AE in the treatment group, and 2 stud- ies reported no AEs.	1314 par- ticipants (8 studies)	⊕ooo very low <sup>b,c</sup>	Could not combine due to lack of da- ta

AC: Active control; AEs: Adverse events; BDI: Beck Depression Inventory; BPI: Brief Pain Inventory; CBT: Cognitive behavioural therapy; CES-D: Centre for Epidemiological Studies - Depression scale; CI: Confidence interval; DASS: Depression Anxiety Stress Scales; FIQ: Fibromyalgia Impact Questionnaire; HADS: Hospital Anxiety & Depression Scale; MPI: Multidimensional Pain Inventory; ODI: Oswestry Disability Inventory; RMDQ: Roland-Morris Depression Questionnaire; SCL-90R: Symptom Check List 90 Revised; SDs: Standard deviations; TAU: Treatment as usual; VAS: Visual Analogue Scale.

**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.

<sup>a</sup>Downgraded once for serious limitations to study quality <sup>b</sup>Downgraded once for serious inconsistency

<sup>c</sup>Downgraded twice for very serious indirectness



# BACKGROUND

# **Description of the condition**

Chronic pain is defined as pain lasting for three months or longer. The most common adult chronic pains include chronic back pain, fibromyalgia, headache, and neuropathic pain. Chronic pain is a global public health problem (Goldberg 2011; Rice 2016), affecting approximately 20% of adults (Eccleston 2017; Macfarlane 2016). The economic burden of chronic pain is calculated as between EUR 1800 and EUR 10,200 per patient per year, depending on country and severity, making it one of the most expensive long-term health conditions by population (Azevedo 2016; Bernfort 2015; Mayer 2014).

The International Classification of Diseases 11th Revision (WHO 2019) included a significant update and reform of the classification of chronic pain, with a distinction between primary pain, in which pain is the primary presenting feature, and secondary pain, which includes pain persisting after surgery or known trauma or pain associated with an identified disease or its treatment (Treede 2019). Whether primary or secondary, chronic pain is associated with mortality when severe (Torrance 2010) and adults with chronic pain who attend pain clinics report high levels of distress, disability and loss of social role (Froud 2014).

# **Description of the intervention**

There is a broad family of treatments included in the general term 'psychological.' In practice, there is variety in the types of intervention used, and not all have been evaluated for their efficacy and safety. The evidence base for psychological therapies is dominated by studies of treatment programmes, with protocols, in a behavioural or cognitive behavioural tradition of clinical psychology. Psychological therapies are commonly offered after orthodox treatments have failed, when the treatment goal shifts from analgesia to: the management of pain; reducing adverse consequences of pain on the patient's quality of life; amelioration of chronic mood disturbance and disability; and the promotion of skills to mitigate or prevent further distress and disability.

A typical treatment protocol for cognitive behavioural therapy (CBT) for adult chronic pain will involve: a) methods of cognitive appraisal which directly assess, reality-test and, where necessary, revise the self-defeating beliefs about and repetitive thoughts associated with pain; b) strategies of emotional regulation or coping, and exposure to reduce the anticipation, expectation and avoidance of unpleasant thoughts about predicted pain; c) behavioural activation to promote engagement with rewarding activities; and d) skills in problem-solving, and motivation. Behavioural therapy (BT) focuses on the identification and reduction of disabling behaviours contingent on pain or worry about pain, or that are strengthened by the short-term benefits of withdrawal or avoidance. Acceptance and commitment therapy (ACT) is an extension of CBT, with a focus on flexibility in action, a willingness to experience pain without struggle, the recognition that thoughts are not facts but are open to interpretation, and the promotion of values-based action. Psychodynamic-orientated treatments may include content aimed at increasing awareness of emotional conflict of which patients are thought to be unaware. There are multiple techniques, many of which involve remembering personal events with a focus on emotional rather than narrative content.

Most psychological therapies involve education about pain, disability, and distress. Many therapies are incorporated within larger treatment programmes involving physical and occupational therapy, and stress (arousal) management.

# How the intervention might work

The design of psychological treatments is normally informed by specific theories of the aetiology and maintenance of human behaviour, though some treatments have developed pragmatically through observation and study of responses to intervention. CBT and BT are designed to help people manage pain, distress and disability. These therapies were first introduced over 50 years ago and are established on experimentally-determined learning principles for human behaviour (Main 2014). Behaviour, often all classes of behaviour, in the context of pain becomes externally controlled, leaving individuals without a sense of personal control or self-efficacy (Martinez-Calderon 2018). Patients may develop patterns of behaviour with the goal of escaping pain but these paradoxically increase their disability and distress (Eccleston 2007). Multiple techniques are deployed with the goal of instilling or restoring self-management skills and confidence. ACT extends these learning principles with a focus on increasing psychological flexibility (McCracken 2014) and on linguistic construction of contextualised and value-determined action, informed by Relational Frame Theory (Hayes 2004).

CBT, BT and ACT all focus on the learning influences that shape and maintain current behaviour, and are agnostic at best about the personal or interpersonal history of that behaviour. There are many forms of psychotherapy that focus specifically on early life adverse experiences, unexplored conflicting emotions and beliefs, and an examination of their effect on current and future behaviour. They are relatively undeveloped in chronic pain management but trials are now emerging (Lumley 2019).

# Why it is important to do this review

Chronic pain is a treatment-resistant condition (Moore 2013). People are often rigidly held in unhelpful patterns of behaviour that substantially increase their risk of over-treatment, multi-morbidity and mortality (Borsook 2018). Psychological interventions promote self-management through behaviour change. Determining the evidence for the different forms of psychological treatment, and for its quality, can help guide patients, clinicians and policy-makers.

The first version of this review was published in 2009 (Eccleston 2009a), and was updated in 2012 (Williams 2012). The review was stabilised because of concerns about the poor quality of studies being produced (Eccleston 2017a). However, the decision to stabilise had no discernible effect on the production of new studies while, paradoxically, the evidence base was considered likely to be out-of-date rather than stable. We therefore chose to update the review. Because this is a second update, with a change in planned analyses, we published a protocol for the update prior to any search or analysis (Williams 2018).

This review is part of a family of reviews on the efficacy of psychological therapies for people with chronic pain, including therapies for migraine in adults (Sharpe 2019), therapies delivered via the Internet for adults (Eccleston 2014), therapies delivered remotely for children (Fisher 2019), and therapies delivered primarily face-to-face for children (Fisher 2018).



# OBJECTIVES

To determine the clinical efficacy and safety of psychological interventions for the treatment of chronic pain in adults (age  $\geq$  18 years) compared with active, waiting list, or treatment-as-usual (TAU) controls.

# METHODS

# Criteria for considering studies for this review

# **Types of studies**

We published a protocol in Prospero before conducting this update of the review (Williams 2018).

We included randomised controlled trials (RCTs) comparing a credible psychological treatment, or a compound treatment with primary psychological content, with placebo, other active treatment, TAU, or waiting list controls. We excluded studies if they were concerned with headache or associated with pain from malignant diseases. We excluded studies that were conducted remotely (phone, Internet, app, or equivalent) since these are reviewed elsewhere (Eccleston 2014; Macea 2010). We judged a psychological model or framework, and was delivered by a health care professional qualified in psychology, or by another health care professional with some psychology training and supervised by a health care professional qualified in psychology.

We included studies that met the following criteria:

- they were available as full publications or reports of an RCT;
- they had a design that placed a psychological treatment as an active treatment of primary interest;
- they had a face-to-face psychological treatment with definable psychotherapeutic content;
- they were published (or electronically pre-published) in a peerreviewed science journal;
- they included participants reporting chronic pain (i.e. of at least three months' duration); and
- they had 20 or more participants in each treatment arm at the end-of-treatment assessment.

We kept the minimum criterion of 20 participants per arm at the end of treatment assessment, as in the 2012 update (Williams 2012). We excluded studies with less than 20 participants at the end of treatment, because of the recognised risk of bias of small numbers (loannidis 2005; Nuesch 2009). Raising the required number of participants post-treatment further would have been desirable, but would have excluded too many studies.

# **Types of participants**

We included adults (age  $\geq$  18 years) reporting pain of at least three months' duration in any body site, not associated with a malignant disease. We excluded patients with only headache or migraine because the psychological treatments and outcomes for these are sufficiently different.

#### **Types of interventions**

We included studies if at least one trial arm consisted of a psychological intervention, with at least one comparator arm

of a placebo condition, other active treatment, TAU or waiting list control. Psychological interventions were classed as any intervention with specific content that is designed following a psychological theory of behaviour and behaviour change. A typical example of a treatment with psychological content is a coping skills training intervention based on behaviour theory and cognitive theory, developed by an experienced clinical psychologist, and delivered by junior psychologists who were supervised by a senior and experienced psychologist. At least 50% of the content had to be psychology, recognising that often such treatments are delivered as packages of care alongside education, rest, exercise, relaxation, etc. A typical example of a treatment with insufficient psychological content is a mindfulness meditation treatment that refers only to education and meditation practice and has no theory to support behaviour change; or a treatment that refers to cognitive behavioural principles but is delivered by an unsupervised nonpsychologist and has no recognisable psychological content. That said, we recognise that some trials of ACT may have components of mindfulness meditation. In these cases, we included multicomponent trials if the mindfulness component was no more than 20% of its overall content.

We compared interventions with two classes of comparator treatments labelled active control (AC) and TAU, using study authors' classifications. AC provides a non-psychological treatment designed to change pain behaviour, such as physical therapy, education or a medical regime. Patients randomised to AC within each trial all received the same treatment. For patients assigned to a waiting list or TAU (both collectively abbreviated to TAU), trials vary in whether this implies regular care, and patients vary in whether they seek further care (from regular consultations to access to care), or use non-prescribed medication and complementary or alternative treatment. Thus patients in these conditions receive variable and usually unrecorded treatment that may in some cases be equivalent to AC.

For crossover trials, we planned to use only the first phase, before crossover. For cluster-randomised trials, we sought evidence of equivalence of treatment and comparison groups at baseline.

#### Types of outcome measures

We defined these outcomes in line with the previous two versions of this review, and with reference to the core outcome domains and measurement recommendations in the field (Dworkin 2005).

#### **Primary outcomes**

- Pain intensity (e.g. Visual Analogue Scales (VAS), McGill Pain Questionnaire (MPQ))
- Disability (e.g. Brief Pain Inventory (BPI) interference items)
- Distress (e.g. Beck Depression Inventory (BDI))
- Adverse events (e.g. worse pain) and dropouts, an unknown proportion of which are attributable to dissatisfaction or unrecorded worse pain, distress or disability.

#### Secondary outcomes

We did not include any secondary outcomes in this review.

# Search methods for identification of studies

# **Electronic searches**

For this update we searched the following databases for RCTs of any psychological therapy for this update:

- Cochrane Central Register of Controlled Trials (CRSO) 2011 to April 2020;
- MEDLINE (OVID) Sept 2011 to 16 April 2020;
- Embase (OVID) Sept 2011 to 16 April 2020;
- PsycINFO (OVID) 2011 to 16 April 2020.

The search strategies, which were run without language restrictions, are provided in Appendix 1. A description of previous searches is available in previous versions of this review (Eccleston 2007; Morley 1999; Williams 2012).

# Searching other resources

We identified additional studies from the reference lists and citations searches of retrieved papers and from discussion with investigators. We also searched online trial registries including clinicaltrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/). We searched these databases in November 2018.

# Data collection and analysis

# **Selection of studies**

We automatically included the trials used in the previous Cochrane Review (Williams 2012), provided that they still met the eligibility criteria for this review. For post-2012 studies, three review authors (AW, EF, LH) independently determined eligibility by reading the abstract of each study identified by the search. Review authors independently eliminated studies that clearly did not satisfy inclusion criteria, and obtained full copies of the remaining studies. All review authors read and agreed on included studies. We did not anonymise the studies in any way before assessment. We included studies in the review, irrespective of whether they measured outcome data in a form that we were able to analyse.

# Data extraction and management

Three review authors (AW, EF, LH) independently extracted data, using a standard form, and checked for agreement before entry into Review Manager (RevMan 2014). In the event of disagreement, a fourth author (CE) adjudicated. We extracted the following information:

- design of the study;
- participants' characteristics (e.g. age, sex);
- primary diagnosis;
- method of treatment; and
- outcome measurement tools used.

We also extracted data relating to our chosen outcomes. For disability outcomes, we preferentially extracted disability measures if they were used. Where no disability/interference/ impact score was available, we extracted the physical component of the SF-36, or a physical component of quality of life, or whole scale if the content seemed appropriate (although this was unlikely as most included subscales assessing psychological wellbeing). For distress outcomes, we preferentially extracted measures that combined anxiety and depression. If these were not reported, we extracted depression measures, followed by anxiety measures.

# Assessment of risk of bias in included studies

We assessed risk of bias (RoB) using the recommended Cochrane guidance (Higgins 2017). We assessed for failure to include sufficient details of trial conduct to counter known biases. We assessed the potential for bias by the extent to which these countermeasures had been reported on, and the adequacy of the method taken. Two authors (AW, EF, or LH) independently assessed RoB for each study using the 'Risk of bias' tool in Review Manager (RevMan 2014).

For this review, we assessed the following sources of bias with the following judgements. We did not assess performance bias (blinding of participants and personnel: the blinding of both patients and therapists to any knowledge of what treatment is being delivered). Although we recognise that biases from the performance of agents in the trial, in particular in actions that allow knowledge of which treatment is being delivered or received, can bias the trial outcomes, the standard counter-methods for managing this bias used in the Cochrane RoB tool are not relevant to psychological therapy interventions where informed consent requires description of each treatment. Instead, we chose to assess treatment expectations because, if these were different between groups, they might have influenced engagement and motivation for a particular arm of a trial.

- Random sequence generation (checking for possible selection bias): We assessed the method used to generate the allocation sequence as: low RoB (any truly random process, e.g. random number table; computer random number generator); unclear RoB (method used to generate sequence not clearly stated). We excluded studies that used a non-random process (e.g. odd or even date of birth; hospital or clinic record number).
- Allocation concealment (checking for possible selection bias): We judged whether the method used to conceal allocation to interventions prior to assignment determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as: low RoB (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear RoB (method not clearly stated). We rated studies that did not conceal allocation (e.g. open list) as high RoB.
- Blinding of outcome assessors (checking for possible detection bias in the measurement of outcome): We judged whether outcome assessors were blinded to treatment allocation as low RoB (outcome assessors were blinded), unclear RoB (no statement about whether outcome assessors were blinded), or high RoB (statement that assessors knew of treatment allocation).
- Incomplete outcome data (checking for possible attrition bias due to the amount, nature, and handling of incomplete outcome data): We assessed the methods used to deal with incomplete data as being at low RoB (fewer than 10% of participants did not complete the study, or authors used 'baseline observation carried forward' analysis, or both), unclear RoB (e.g. used 'last observation carried forward' (LOCF) analysis), or high RoB (e.g. used 'completer' analysis) (Nuesch 2009).



- Selective reporting (checking for reporting bias): We assessed whether primary and secondary outcome measures were pre-specified and whether these were consistent with those reported. We judged studies that were pre-registered or had a protocol publicly available and reported the same outcomes as in the protocol as low RoB. We judged studies that did not refer to a pre-registered protocol as unclear RoB, and those studies that had a pre-registered or available protocol but where outcomes did not match between protocol and paper, or were reported in a different order (i.e., primary outcomes in the protocol reported as secondary outcomes in the paper) as high RoB.
- Treatment expectations: Expectations of benefit can affect outcomes. Since they may differ significantly between treatment and control conditions, we judged studies for their assessment of treatment expectations across all trial arms. We assessed studies as low RoB if there were no significant differences between arms on treatment expectations, unclear RoB if study authors assessed expectations and found differences between arms, or if no assessment was made for treatment expectations. We did not rate any studies as high RoB for this category.

#### **Measures of treatment effect**

The previous version of this review investigated two classes of psychological treatments: CBT and BT. In this update, we added the class of the treatment labelled ACT. Further, there are psychological therapies that are not recognisable as CBT, BT or ACT, or or not defined as such by their originators or practitioners. For such therapies, we created a category of 'other.' By definition, this category is small and heterogeneous. We did not attempt metaanalysis of studies in this category but provided a narrative review.

We selected two assessment time-points: at the end of treatment and at follow-up. 'At the end of treatment' was the assessment point immediately following treatment, and 'at follow-up' was the assessment point at least six months after the end of treatment, but not more than 12 months, and the longer of the two if there were two follow-up assessments within this time frame.

Therefore, we conducted twelve separate comparisons, comprising three classes of psychological treatment under investigation: CBT, BT, and ACT. These are compared with two forms of comparator: active comparators (AC) including sham or active treatments; and TAU. Thus, each treatment was compared with AC or with TAU at two time-points, immediately at the end of treatment (T1) and at follow-up as described above (T2). We combined data in a meta-analysis using standardised mean differences (SMD) and 95% confidence intervals (CI) where possible. We conducted analyses for each of the comparisons below. Where a meta-analysis was not suitable, we described findings from studies qualitatively. The six comparisons were:

- 1. CBT versus AC at T1 and T2;
- 2. CBT versus TAU control at T1 and T2;
- 3. BT versus AC at T1 and T2;
- 4. BT versus TAU control at T1 and T2;
- 5. ACT versus AC at T1 and T2; and
- 6. ACT versus TAU control at T1 and T2.

The primary data type was measurement using continuous scales. We estimated treatment effects using SMDs by extracting means,

standard deviations (SD) and sample sizes at the end of treatment and at follow-up. Dichotomous outcome data based on clinical improvement were rare but, if they existed, we extracted these.

Multiple measurement tools are typically used in each trial. For each comparison, we identified four outcomes, labelling them 'pain,' 'disability,' 'distress,' and 'adverse events.' Although standard trial reporting guidance promotes the definition of primary outcomes (Boutron 2008), most trials do not state a single or preferred a priori primary outcome, so we made a judgement. From each trial, we selected the scale considered most appropriate for each of the three outcomes. When there was more than one scale for an outcome, we gave preference to the scales most widely used in the field over scales rarely used or unique to the study, and/or to scales used by other studies in the same analysis, in order to reduce heterogeneity. Also, when there was a choice between single-item and multi-item self-report tools, we chose longer tools on the basis of inferred increased reliability. Not all trials reported data on all four outcomes of pain, disability, distress, and adverse events, or reported follow-up data.

#### Unit of analysis issues

The unit of evaluation was the participant. Where a trial had more than two arms, we selected those that best matched our requirements for therapies and, where there was a choice, the most intensive version of either. For example, if a trial had an enriched CBT (that is, CBT with additional non-core components such as vocational guidance), a minimum CBT and a waiting list condition, we compared the enriched CBT with the waiting list. If both options seemed similarly 'intensive,' we followed the Cochrane Handbook guidance (Higgins 2011 section 16.5.4) and included multiple relevant arms in the same analysis, if necessary; for example, by splitting the control group data. For clusterrandomised controlled trials, we sought evidence of equivalence of participants in treatment and comparison groups at baseline.

#### Dealing with missing data

We contacted study authors where there were missing data.

# Assessment of heterogeneity

We assessed heterogeneity according to the standard method using the  $\chi^2$  test and the I<sup>2</sup> statistic, calculated for each comparison on each outcome. We interpreted I<sup>2</sup> values according to the Cochrane Handbook (Higgins 2011):

- 0% to 40%: heterogeneity might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

# Assessment of reporting biases

We planned to assess reporting biases by assessing funnel plots if there were sufficient studies for such an analysis.

# **Data synthesis**

We combined SMD data using random-effects models, due to the differences in populations and measures used in the included studies. We reported 95% CI, and I<sup>2</sup>.

### Subgroup analysis and investigation of heterogeneity

We did not plan any subgroup analyses because there is no strong *a priori* reason in the literature to analyse the data by population (e.g. type of pain, age). It is unlikely that subgroup analyses would help to further understand the estimate of effects. However, we explored heterogeneity through sensitivity analyses.

# Sensitivity analysis

We planned to explore the influence of expected imprecision in measurement that should obtain from the relatively low number of participants at entry to studies with 20 participants with further sensitivity analyses based on a minimum of 50 participants in the treatment arm at the time point being compared (T1 or T2). We also ran sensitivity analyses on analyses that included clear outliers.

# Summary of findings and assessment of the quality of the evidence

In this update, all reviewers discussed the quality of the evidence and agreed on ratings for each analysis. We used the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) system to rank the quality of the evidence, and the guidelines provided in the Cochrane Handbook for Systematic Reviews of Interventions (Chapter 11) (Schünemann 2017). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence for each outcome. The GRADE system uses the following criteria for assigning grade of evidence:

- high: we are very confident that the true effect lies close to the estimate of the effect;
- moderate: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different;
- low: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect;
- very low: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Factors that may decrease the quality level of a body of evidence are:

- limitations in the design and implementation of available studies, suggesting high likelihood of bias;
- indirectness of evidence (indirect population, intervention, control, outcomes);
- unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses);
- imprecision of results (wide confidence intervals);
- high probability of publication bias.

We decreased the grade rating by one (-1) or two (-2) (up to a maximum of -3 to 'very low') if we identified:

- serious (-1) or very serious (-2) limitations to study quality;
- serious (-1) or very serious (-2) inconsistency;
- serious (-1) or very serious (-2) uncertainty about directness;
- serious (-1) or very serious (-2) imprecision;
- high probability of reporting bias (-1).

# 'Summary of findings' table

We included two 'Summary of findings' (SoF) tables to present the findings for CBT versus AC and CBT versus TAU. In particular, we included key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the outcomes of pain intensity, disability, and distress, all at end of treatment and at follow-up, and AEs at end of treatment.

# Summary of findings and assessment of the certainty of the evidence

In this update, all reviewers discussed the quality of the evidence and agreed on ratings for each analysis. We used the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) system to rank the quality of the evidence, and the guidelines provided in the Cochrane Handbook for Systematic Reviews of Interventions (Chapter 11) (Schünemann 2017). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence for each outcome. The GRADE system uses the following criteria for assigning grade of evidence:

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# RESULTS

# **Description of studies**

See Characteristics of included studies; Characteristics of excluded studies.

# **Results of the search**

For a description of the search results for this review's previous version, see Williams 2012. In the current review, searches of the four databases retrieved 6881 records (see Electronic searches). Our searches of other resources (reference and citation searches of included studies) identified 15 additional studies that appeared to meet inclusion criteria. After removing duplicates, we retained 6018 records. We excluded 5930 records based on titles and abstracts. We obtained the full text of the remaining 88 records. We excluded 39

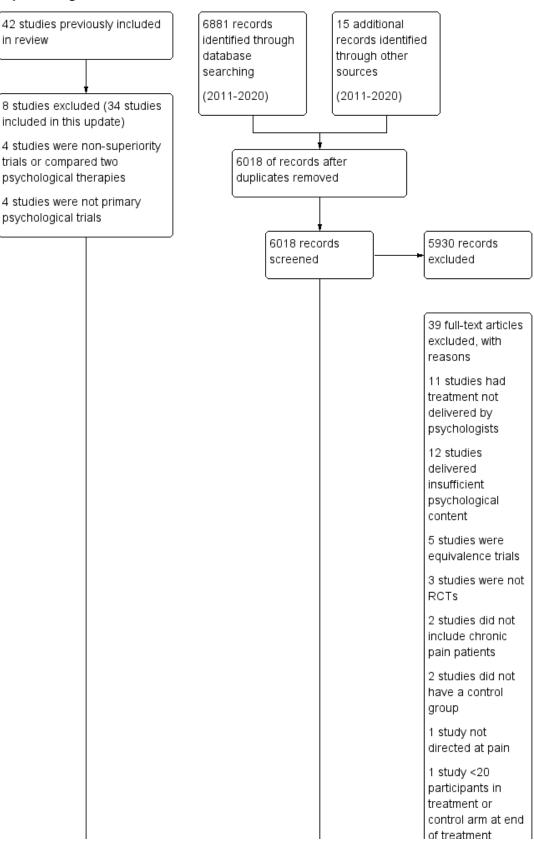
studies (see Characteristics of excluded studies), and incorporated 49 new papers which reported on 41 new trials.

We added these trials to the previously included studies from this review. There were 42 studies in the previous update. We included 34 of these studies in this update. We excluded four trials from the previous review because they were equivalence trials with no control arm or compared two psychological therapies to each other, without adequate control (Ehrenborg 2010; Leeuw 2008; Jensen 1997; Wetherell 2011) and four further trials because they were not primary psychological interventions (Falcao 2008; Hammond 2001; McCarberg 1999, Schmidt 2011).

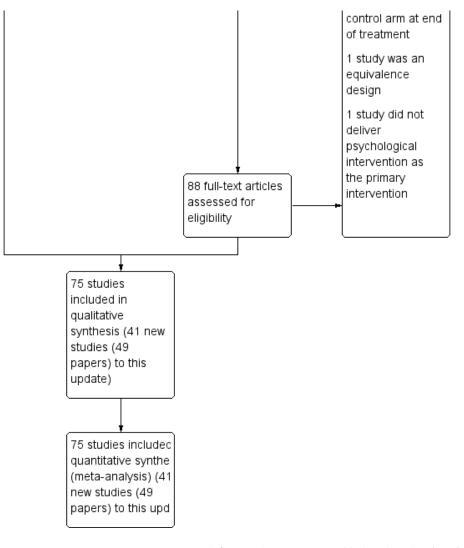
Therefore, we included 75 studies in this update (41 new studies and 34 studies from the previous update). For a further description of our screening process, see the study flow diagram (Figure 1). In addition, we searched trial registries for ongoing trials and added four trials to Characteristics of studies awaiting classification and two trials to Characteristics of ongoing studies.



# Figure 1. Study flow diagram.







#### **Included studies**

We included 41 new studies in this review (pre-treatment n = 6255; end of treatment n = 5475), resulting in a total of 75 studies in this update (pre-treatment n = 10,708; end of treatment n = 9401). This resulted in a mean of 143 participants entering treatment, and 125 participants finishing treatment, per study. This was an increase on the previous update of this review, which found a mean of 114 participants completing treatment per study. Attrition ranged from 0% to 48% (mean attrition across studies: 12%). Women (n = 7269) outnumbered men (n = 3004) in 65 of the 75 studies (one trial did not report gender). Mean age was 50.2 years (SD 10.1). The mean length of pain was 9 years (SD = 8), reported by 50 studies.

Most studies had two arms (n = 39), with smaller numbers using three arms (n = 27), and four arms (n = 8). One study (Lumley 2017) was clustered by the time of day preferred for attendance by participants, and showed equivalence across groups on baseline characteristics. There were no crossover studies.

We found a range of chronic pain conditions in the included studies. There were 19 studies with patients with fibromyalgia, 16 with chronic low back pain, nine with rheumatoid arthritis, 15 with mixed chronic pain conditions, five with osteoarthritis, and four with temporomandibular disorder (TMD). There was one study with each of the following conditions: burning mouth syndrome, chronic musculoskeletal pain, chronic prostatitis/pelvic pain, multisomatoform disorder, neuropathic pain, shoulder pain, and systemic lupus erythematosus disease.

The included studies recruited from a range of settings. The majority of studies recruited from hospital settings including pain clinics and/or rehabilitation clinics and other speciality clinics (n = 53). Some studies (n=5) recruited from multiple settings, including advertisements in the community and health charities, and in medical settings. Other studies recruited directly from the community and recruited volunteers (n = 8). Finally, a minority of studies recruited from retirement homes (n = 2), insurance companies (n = 1), or primary care (n = 3). Three studies did not report their recruitment.

We classified treatment arms on the basis of their content and of the label given by the authors as CBT, BT, or ACT. On rereading the content of treatment, we moved one study (Mangels 2009), previously classified as BT, to CBT. All treatment involved a psychologist, whether trained, or in training and supervised, in intervention delivery. We classified control conditions either as



'active control' (AC) when there was a protocolised treatment that engaged the patient, such as an exercise programme, a medical procedure, an education programme, a support group or a selfinstruction booklet; or as 'waiting list or treatment as usual' (TAU). We did not distinguish between waiting list and treatment as usual because, for some patients, treatment as usual is elective treatment that may be no treatment at all, and therefore equivalent to being on a waiting list; and because some studies allow patients on waiting lists to seek other treatment elsewhere, which treatment may be equivalent to that in 'treatment as usual' conditions. We are aware that this is not an entirely satisfactory classification as TAU may involve some active and regular physiotherapy or pharmacotherapy, not dissimilar to those offered in ACs, and where the large majority of patients follow it routinely. However, when available information did not allow us to assign a condition as AC, we classified it as TAU.

We found 50 studies that delivered CBT, seven studies delivering CBT and BT, and two studies delivering CBT and a therapy categorised as 'other.' Six studies delivered BT, six studies delivered ACT, and four studies delivered a therapy categorised as 'other' alone. 'Other' types of therapies were intensive short-term dynamic psychotherapy (Chavooshi 2016), emotional disclosure (Lumley 2014), emotional awareness and expression therapy (Lumley 2017), group psychotherapy (Miziara 2009), and psychodynamic therapy (Sattell 2012; Scheidt 2013). We found 31 studies with ACs, 36 studies with TAU controls, and eight studies with both.

#### **Excluded studies**

In addition to those excluded in the 2012 review, we excluded 47 studies. Thirty-nine of these were studies new to this update.

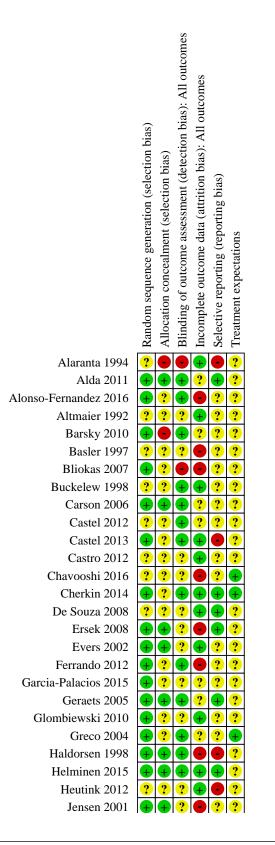
We also excluded eight studies that had previously been included (Ehrenborg 2010; Falcao 2008; Hammond 2001; Leeuw 2008; Jensen 1997; McCarberg 1999; Schmidt 2011; Wetherell 2011). Disregarding those that did not meet inclusion criteria (e.g. did not primarily concern chronic pain, were not randomised, were non-inferiority trials, had too few participants at the end of treatment, had no suitable control group, did not deliver a psychological intervention as the primary intervention, that were trials of hypnosis or were delivered by phone or Internet), 12 new studies initially appeared to be trials of CBT or BT. However, our examinations of the full papers found that these studies failed to meet our criteria as credible psychological treatments (e.g. Garland 2013; Torres 2018) or not delivered by a psychologist (e.g. Bourgault 2015; Harris 2017; Haugli 2000. While the initial inclusion of these studies from the search is in part evidence of the diversity of terminology used to describe pain and treatments, it also raises important issues about nonspecific design features that potentially undermine the content, or fail to deliver what is implied by the description of treatment; and highlights the inevitably blurred boundaries between psychological intervention and education, instruction or nonspecific support. This judgement was difficult to apply in some cases, and led to extended discussion among the review authors to reach a decision.

#### **Risk of bias in included studies**

'Risk of bias' findings are shown in Figure 2 and Figure 3. We judged six RoB 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). We also judged treatment expectations in this update.



Figure 2. 'Risk of bias' summary: review authors' judgements about each methodological quality item for each included study.





# Figure 2. (Continued)

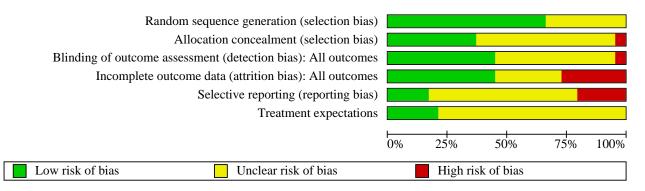
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Turner 1988 Turner 2006		••••••••••••••••••••••••••••••••••••••	• ?	• ?	• ?
van Eijk 2013		+ <mark>·</mark> + ?	• ?		<u>·</u> ?
Van Koulil 2010	+ ?	• ? ?			<u>·</u> ?
Vitiello 2013		· ?			<u>·</u> ?
Vlaeyen 1996	$\frac{1}{2}$	• <b>•</b> 2 2		<b>1</b> 2	
v laeyen 1990		• •		•	



# Figure 2. (Continued)

Vitiello 2013	Ŧ	<mark>?</mark>	+	+	+	<mark>?</mark>
Vlaeyen 1996	?	?	?	Ŧ	?	Ŧ
Wang 2018	Ŧ	?	?	Ŧ	•	?
Wiklund 2018	?	?	?	?	•	?
Williams 1996	Ŧ	?	ŧ	•	?	+
Zautra 2008	Ŧ	?	Ŧ	Ŧ	Ŧ	?

# Figure 3. 'Risk of bias' graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



# Allocation

We assessed random allocation bias and found that 50 studies provided a convincing description of randomisation: we therefore judged these studies to be at low RoB in this domain. We judged the remaining 25 studies as unclear, as they did not provide a convincing description of how participants were randomised.

We judged most studies to be at unclear RoB for allocation concealment. Forty-four studies did not provide a convincing method of concealing allocation from participants. We judged three studies to be at high RoB, and 28 studies to be at low RoB.

#### Blinding

We only judged blinding of outcome assessors. We judged 34 studies to be at low RoB in this domain, as they explicitly stated that they blinded outcome assessors to participant allocation. We judged 38 studies to have unclear RoB, where studies did not explicitly state if or how they blinded outcome assessors from treatment allocation. We judged three studies as having high RoB, as the outcome assessors of those studies knew of participants' allocation.

# Incomplete outcome data

We judged 20 studies as unclear for attrition bias. These studies either had a high level of attrition or used last observations carried forward. We judged 34 of studies to be at low RoB in this domain. These studies had a low level of attrition or used 'baseline observation carried forward.' Finally, we judged 21 studies as having high RoB. These had a high level of attrition and used a 'completer' analysis.

# Selective reporting

We assessed most studies as having unclear risk of selective reporting biases. Forty-seven studies did not pre-register their trial and therefore we were unable to determine whether all outcomes were reported in the trial manuscript. We found 13 studies that we judged as having low RoB in this domain. These studies preregistered their trials or published their protocols and reported all outcomes in the trial manuscript. We judged the other 15 studies as having high RoB, either because they did not fully report all outcomes from the pre-registration in the manuscript or only reported outcomes that reached statistical significance, omitting non-significant findings.

# Other potential sources of bias

# **Treatment expectations**

We also assessed treatment expectations to determine whether the expectations of benefit from intervention were similar across treatment and control groups. Since it is not possible to blind therapists to treatment, and it is rarely possible to blind participants, sampling expectations of benefit from each arm of trials shows whether there are major disparities in expectation of benefit, equivalent to placebo effects. We found that most studies (n = 59) did not assess treatment expectations and therefore we judged them as having unclear RoB in this domain. We judged 16 studies to be at low RoB; these assessed treatment expectations and found no differences between groups. We did not judge any studies as having high RoB.



# **Effects of interventions**

See: Summary of findings 1 Summary of findings: CBT compared with AC for adults with chronic pain; Summary of findings 2 Summary of findings: CBT compared with TAU for adults with chronic pain

See SoF tables for CBT versus AC (Summary of findings 1) and CBT versus TAU (Summary of findings 2). Because of the lack of natural units for outcomes, the absence of healthy norms, and the variety of scales used within each domain, we were unable to translate effects into meaningful minimum important differences (Guyatt 2013).

Below, we outline the effects for each intervention type versus control type at the end of treatment and at follow-up for pain, disability, and distress outcomes, and for AEs. Next, we summarise the outcomes across the comparisons. We have included the quality of evidence in the treatment effects below. Next, we summarise the outcomes across the comparisons.

# **CBT versus AC**

# At end of treatment

We found 23 studies with 3235 participants that provided data on the effects of CBT on pain, compared to AC at the end of treatment. CBT had a very small overall benefit over AC for pain: SMD -0.09 (95% CI -0.17 to -0.01); Z = 2.14 (Analysis 1.1); I<sup>2</sup> was 18%. We found 19 studies with 2543 participants that provided data on the effects of CBT on disability compared to AC. CBT had a small overall benefit over AC for disability: SMD -0.12 (95% CI -0.20 to -0.04); Z = 2.96 (Analysis 1.2); I<sup>2</sup> was 0%. We found 24 studies with 3297 participants that provided data on the effects of CBT on distress compared to AC. CBT showed no overall benefit over AC for distress: SMD -0.09 (95% CI -0.18 to -0.00); Z = 2.02 (Analysis 1.3); I<sup>2</sup> was 35%. Two studies did not report AEs or dropout at all; 21 reported dropout but made no reference to AEs; and one reported no AEs in either the CBT or AC groups (Lumley 2017). One study that compared CBT with both AC and TAU reported AEs (without detail) as the reason for dropout of 5.3% participants in the AC group and 3.6% of participants in the TAU group (Alda 2011); a second reported minor AEs, mostly temporary pain exacerbations, in 10% of the intervention group and in 19% of the control group, such that they sought emergency medical care (Thorn 2018).

We judged evidence for all three outcomes of pain, disability, and distress to be of moderate quality. We downgraded each once for serious limitations to study quality. We judged evidence for AEs to be of very low quality, downgraded twice due to very serious indirectness and once for high probability of selective reporting bias.

# At follow-up

We found 16 studies with 2362 participants that provided data on the effects of CBT on pain at follow-up of 6 months or more, compared to AC. CBT showed no evidence of benefit over AC: SMD -0.08 (95% CI -0.19 to 0.04); Z = 1.32 (Analysis 1.4); I<sup>2</sup> was 42%. We found 15 studies with 1919 participants that provided data on the effects of CBT over AC on disability at follow-up. CBT showed no benefit over AC: SMD -0.12 (95% CI -0.26 to 0.02); Z = 1.67 (Analysis 1.5); I<sup>2</sup> was 53%. We found 16 studies with 2362 participants that provided data on the effects of CBT compared to AC on distress at follow-up. CBT showed a very small benefit over AC: SMD -0.13 (95% CI -0.25 to -0.01); Z = 2.10 (Analysis 1.6); I<sup>2</sup> was 48%. We judged evidence for pain and distress outcomes to be of moderate quality; downgraded once for serious limitations to study quality. We judged evidence for disability to be of low quality; we downgraded twice, once for serious limitations to study quality and once for serious inconsistency.

# **CBT versus TAU**

# At end of treatment

We found 29 studies with 2572 participants that provided data on the effects of CBT on pain at the end of treatment. CBT showed a small benefit over TAU: SMD -0.22 (95% CI -0.33 to -0.10); Z = 3.76 (Analysis 2.1); I<sup>2</sup> was 50%. We found 28 studies with 2524 participants that provided data on the effects of CBT over TAU on disability. CBT showed a small benefit over TAU: SMD -0.32 (95% CI -0.45 to -0.19); Z = 4.86 (Analysis 2.2); I<sup>2</sup> was 61%. We found 27 studies with 2559 participants that provided data on the effects of CBT on distress; CBT showed a small benefit over TAU: SMD -0.34 (95% CI -0.44 to -0.24); Z = 6.63 (Analysis 2.3); I<sup>2</sup> was 36%.

Five studies did not report at all on AEs or dropout. Twenty-four studies reported dropout but made no reference to AEs. Eight studies provided information about AEs. Two studies reported explicitly that there were no AEs in their studies (Helminen 2015; Wang 2018). One study that compared CBT with both AC and TAU reported AEs (without detail) as the reason for dropout of 5.3% participants in the AC group and 3.6% of participants in the TAU group (Alda 2011). One study noted higher pain ratings in participants who dropped out of either arm of the trial (Basler 1997). One study reported minor and transitory AEs in 10% of the intervention group and 30% of the control (yoga) group (Cherkin 2014). One study reported that three participants in each active treatment condition withdrew due to reported lack of treatment benefit, but no significant harms were reported (Macrae 2019). One study reported minor injury when a participant fell off a treadmill in the intervention condition (Somers 2012). One study reported minor AEs, mostly temporary pain exacerbations, in 10% of the intervention group and 18% of the control group, such that they sought emergency medical care (Thorn 2018).

We judged evidence for outcomes of pain and distress to be of moderate quality: we downgraded each once for serious limitations to study quality. We judged evidence for disability to be of low quality, downgraded once for serious limitations to study quality and once for serious inconsistency. We judged evidence for AEs to be of very low quality, downgraded once for serious inconsistency and twice due to very serious indirectness.

# At follow-up

We found 15 studies with 1674 participants that provided data on the effects of CBT on pain at follow-up of 6 months or more. CBT showed a very small benefit over TAU: SMD -0.16 (95% CI -0.27 to -0.04); Z = 2.69 (Analysis 2.4); I<sup>2</sup> was 23%. We found 15 studies with 1581 participants that provided data on the effects of CBT on disability at follow-up. There was a small benefit of CBT over TAU: SMD -0.21 (95% CI -0.37 to -0.05); Z = 2.59 (Analysis 2.5); I<sup>2</sup> was 57%. We found 16 studies with 1757 participants that provided data on the effects of CBT on distress. CBT showed a small benefit over TAU: SMD -0.25 (95% CI -0.37 to -0.13); Z = 4.08 (Analysis 2.6); I<sup>2</sup> was 36%.

We judged the evidence for pain and for distress to be of moderate quality; we downgraded once for serious limitations to study



quality. We judged the evidence for disability to be of low quality; we downgraded twice, once for serious limitations to study quality, and once for serious inconsistency.

# **BT versus AC**

# At end of treatment

We found two studies with 144 participants that provided data on the effects of BT on pain at the end of treatment. There was no evidence of difference between BT and AC for pain: SMD -0.67 (95% CI -2.54 to 1.20); Z = 0.70 (Analysis 3.1); I<sup>2</sup> was 96%. We found three studies with 215 participants that provided data on the effects of BT on disability. There was no evidence of difference between BT and AC for disability: SMD -0.65 (95% CI -1.85 to 0.54); Z = 1.07 (Analysis 3.2); I<sup>2</sup> was 94%. We found three studies with 215 participants that provided data on the effects of BT on distress (Analysis 3.3). There was no evidence of difference between BT and AC for distress: SMD -0.73 (95% CI -1.47 to 0.01); Z = 1.94; I<sup>2</sup> was 85%. One study reported dropouts without reasons and four reported dropouts with reasons, but AEs were not noted in this context. No other AEs were reported.

We judged the quality of evidence to be very low for pain, disability and distress at both time-points. We downgraded outcomes three times, twice for serious inconsistency and once for serious imprecision. We rated evidence for AEs in this comparison as very low quality, downgraded twice due to very serious indirectness and once for serious imprecision.

# At follow-up

We found two studies with 144 participants that provided data on the effects of BT on pain at follow-up of six months or more. There was no evidence of difference between BT and AC for pain: SMD -0.36, (95% CI -1.02 to 0.30); Z = 1.07 (Analysis 3.4); I<sup>2</sup> was 73%. We found three studies with 212 participants that provided data on the effects of BT on disability at follow-up. BT showed large benefit over AC for disability: SMD -1.09 (95% CI -2.03 to -0.15); Z = 2.27 (Analysis 3.5); I<sup>2</sup> was 90%. We found three studies with 212 participants that provided data on the effects of BT on distress at follow-up. BT showed large benefit over AC on distress: SMD -0.90 (95% CI -1.47 to -0.33); Z = 3.12 (Analysis 3.6); I<sup>2</sup> was 74%.

Similar to end-of-treatment findings, we judged the quality of evidence to be very low for all outcomes. For pain, we downgraded once for serious inconsistency and twice for very serious imprecision. For disability, we downgraded twice for very serious inconsistency and once for serious imprecision. For distress, we downgraded once due to serious limitations in study quality, once for serious inconsistency, and once for serious imprecision.

# **BT versus TAU**

# At end of treatment

We found three studies with 308 participants that provided data on the effects of BT on pain at end of treatment. There was no evidence of difference between BT and TAU: SMD -0.08 (95% CI -0.33 to 0.17); Z = 0.61 (Analysis 4.1); I<sup>2</sup> was 16%. We found four studies with 379 participants that provided data on the effects of BT on disability. There was no difference between BT and TAU: SMD -0.02 (95% CI -0.24 to 0.19); Z = 0.21 (Analysis 4.2); I<sup>2</sup> was 7%. We found two studies of 153 participants that provided data on the effects of BT on distress. There was no evidence of difference between BT and TAU: SMD 0.22 (95% CI -0.10 to 0.54); Z = 1.37 (Analysis 4.3);  $I^2$  was 0%. All studies but one reported dropouts from treatment; none provided any information on AEs.

We judged the quality of evidence to be low for the outcomes of pain and distress. We downgraded twice, once for serious limitations to study quality, and once for serious indirectness. We judged disability as moderate-quality evidence, downgraded once for serious limitations to study quality. We could not make a GRADE analysis on AEs as no studies reported any in this comparison.

#### At follow-up

We found one study with 102 participants that provided data on the effects of BT on pain at follow-up. No new studies contributed to this analysis so we could not run a meta-analysis (Analysis 4.4). We found three studies with 329 participants that provided data on the effects of BT on disability. There was no evidence of difference between BT and TAU: SMD 0.14 (95% CI -0.18 to 0.46); Z = 0.88 (Analysis 4.5); I<sup>2</sup> was 47%. We found two studies with 153 participants that provided data on the effects of BT on distress at follow-up. There was no evidence of difference between BT and TAU: SMD 0.26 (95% CI -0.06 to 0.57); Z = 1.57 (Analysis 4.6); I<sup>2</sup> was 0%.

We judged the quality of evidence for pain and distress to be very low. We downgraded three times, once for serious indirectness and twice for very serious imprecision. We judged disability to be of moderate-quality evidence, downgraded due to serious indirectness.

# **ACT versus AC**

# At end of treatment

We found five studies with 385 participants that provided data on the effects of ACT compared to AC on pain at the end of treatment. There was no evidence of difference between ACT and AC: SMD -0.54 (95% CI -1.20 to 0.11); Z = 1.62 (Analysis 5.1);  $I^2$  was 89%. We found four studies with 260 participants that provided data on the effects of ACT compared to AC on disability at the end of treatment. There was no evidence for difference between ACT and AC: SMD -1.51 (95% CI -3.05 to 0.03); Z = 1.92 (Analysis 5.2); I<sup>2</sup> was 96%. We found five studies with 385 participants that provided data on the effects of ACT compared to AC on distress at the end of treatment. There was no evidence of difference between ACT and active control: SMD -0.61 (95% CI -1.30 to 0.07); Z = 1.75 (Analysis 5.3); I<sup>2</sup> was 90%. Two studies reported that there were no AEs linked to psychological therapy (Luciano 2014; Pincus 2015). The other three studies reported dropout but without reference to AEs (Alonso-Fernandez 2016; Wiklund 2018).

We judged the quality of evidence to be very low for outcomes of pain, disability and distress. We downgraded three times, once for serious limitations to study quality, and twice for very serious imprecision. We rated AEs as very low-quality evidence, downgraded twice due to very serious indirectness and once for serious imprecision.

#### At follow-up

We found three studies with 265 participants that provided data on the effects of ACT compared to AC on pain at follow-up of six months or more. There was no evidence of difference between ACT and AC: SMD -0.38 (95% CI -1.03 to 0.27); Z = 1.15 (Analysis 5.4); I<sup>2</sup>



Similar to end-of-treatment findings, we judged the quality of evidence to be very low: we downgraded three times, once for serious limitations to study quality, and twice for very serious imprecision.

# **ACT versus TAU**

#### At end of treatment

We found two studies with 162 participants that provided data on the effects of ACT compared to TAU on pain at the end of treatment. ACT showed a large benefit over TAU: SMD -0.83 (95% CI -1.57 to -0.09; Z = 2.20 (Analysis 6.1); I<sup>2</sup> was 80%. We found two studies with 162 participants that provided data on the effects of ACT compared to TAU on disability at the end of treatment. There was no evidence of difference between ACT and TAU: SMD -1.39 (95% CI -3.20 to 0.41); Z = 1.51 (Analysis 6.2); I<sup>2</sup> was 96%. We found two studies with 162 participants that provided data on the effects of ACT compared to TAU on distress at the end of treatment. There was no evidence of difference between ACT and TAU: SMD -1.16 (95% CI -2.51 to 0.20); Z = 1.67 (Analysis 6.3);  $I^2$  was 93%. One study (McCracken 2013) reported dropouts but without reference to AEs. The other study (Luciano 2014) reported no AEs in the intervention group but the expected AEs of the medication control, as a result of which 9% left the trial.

We judged the quality of evidence for outcomes of pain, disability and distress to be very low. We downgraded three times, once for serious limitations to study quality, twice for very serious imprecision. We rated the quality of evidence for AEs to be very low, downgraded twice due to very serious indirectness and once for serious imprecision.

#### At follow-up

We found one study with 104 participants comparing ACT to TAU for pain at follow-up of at least six months (Luciano 2014). As there was only one study, we were unable to conduct a meta-analysis.

We judged the quality of evidence to be very low: we downgraded three times, once for serious limitations to study quality, and twice for very serious imprecision.

# Summary of outcomes across comparisons

#### Pain outcomes

CBT had a very small beneficial effect on pain measured immediately at the end of treatment, when compared with either active control or doing nothing (TAU or waiting list). There was no effect at follow-up when compared with AC, but there was a small beneficial effect when compared with TAU. There was no evidence that BT had any effect on pain compared to AC or TAU, at either time-point, with insufficient evidence available for followup assessment of BT versus TAU. There was no evidence that ACT had an effect on pain when compared with AC, but there was a large benefit over TAU, both at the end of treatment, although these results came from only two studies and one study respectively. At follow-up, there was no effect on pain of ACT compared to AC. There was insufficient evidence available for follow-up assessment of ACT vs TAU.

# **Disability outcomes**

CBT had a small beneficial effect on disability at the end of treatment and at follow-up, compared with TAU, and a very small effect at the end of treatment compared with AC, though the latter effect disappeared at follow-up. There was no evidence of a difference between BT and AC or TAU at the end of treatment, or for BT compared to TAU at follow-up. BT versus AC showed evidence of a large beneficial effect at follow-up, but we have no confidence in this finding because of the poor quality of the evidence. ACT had no effect on disability at the end of treatment, either compared with AC or TAU, but a large effect compared to AC at follow-up, although this is based on only two studies (insufficient evidence available for TAU).

# **Distress outcomes**

CBT showed no benefit for distress over AC and a small benefit over TAU immediately after treatment. At follow-up, CBT showed a very small benefit compared to AC and a small benefit compared to TAU. There was no evidence of difference between BT and AC for distress at the end of treatment. There was good benefit at follow-up, but we have no confidence in this finding because of the poor quality of the evidence. There was no evidence of difference between BT and TAU at either time-point. ACT had no evidence of benefit over AC at the end of treatment or at follow-up, nor any benefit over TAU at the end of treatment, though a single study reported a large benefit over TAU at follow-up.

#### Adverse events

Few studies reported actual AEs during treatment. We also extracted data on dropouts since they may be attributable to lack of effect, to unrecorded AEs, or to extraneous causes that are unrelated to adverse events. However, if the reasons for attrition are not collected, this information is unavailable. We extracted data on AEs and attrition from the included studies. Most studies (n = 53) reported dropouts and reasons for these in accounting for numbers at each assessment point, but did not describe these reasons in terms of AEs of allocated treatment or control condition, and did not otherwise mention AEs.

In studies delivering CBT, nine explicitly addressed AEs. Alda 2011 reported withdrawals due to AEs in the control group (pharmacological treatment) including digestive problems and dizziness, and two participants in the TAU group also withdrew due to AEs of unreported nature. Cherkin 2014 reported increase in pain in both conditions. Macrae 2019 reported that three participants in each active treatment condition withdrew due to reported lack of treatment benefit but no significant harms were reported. Thorn 2018 also reported participants across all conditions experiencing increases in pain, infections and suicidal ideation, but attributed none to therapy. Helminen 2015 reported that no AEs occurred. Somers 2012 reported one participant falling off the treadmill during a study exercise session, resulting in superficial wounding. Helminen 2015, Lumley 2017, and Wang 2018 reported no AEs in the CBT condition. Alda 2011, Lumley 2017, and Thorn 2018 compared CBT to AC. Alda 2011, Basler 1997, Cherkin 2014, Helminen 2015,



Macrae 2019, Somers 2012, Thorn 2018, and Wang 2018 compared CBT to TAU.

No studies delivering BT explicitly addressed AEs. Most studies reported dropouts but did not report whether there were any AEs.

We found two studies that explicitly reported AEs for ACT interventions. The first delivered ACT compared to AC and recorded that no AEs were reported by participants (Pincus 2015). The second study compared ACT to AC and TAU and reported no serious AEs (Luciano 2014). In the control arm (recommended pharmacological treatment), however, they noted AEs including nausea (25%), dry mouth (23.1%), drowsiness (21.2%), constipation (19.2%), headache (21.2%), and fatigue (21.2%). Further, five participants withdrew from the study in the control arm due to AEs (Luciano 2014). No AEs were noted in the psychological condition.

Finally, Lumley 2017 reported an increase in pain in the Emotion Awareness category.

#### Sensitivity analyses

We initially included three additional CBT versus AC studies (401 participants) in our analyses (Monticone 2013; Monticone 2016; Monticone 2017), and one study of 92 participants in CBT versus TAU (Castel 2012), but all were extreme outliers, with no overlap of CIs with any other study in the analysis, and raising the heterogeneity to very high values. We suspected that the Castel 2012 study misreported standard errors of measurement as SDs, inflating the SMD, but were unable to obtain an answer from authors concerning the study. For Monticone 2013, Monticone 2016, and Monticone 2017, no explanations were offered by the authors as to why the data were major outliers from all other studies in the field and, in particular, why the efficacy estimates were so positive and why there was no attrition, unlike other studies. We excluded them from the results above but included them in sensitivity analyses here for comprehensiveness. The results are shown in Table 1 and Analysis 7.1; Analysis 7.2; Analysis 7.3; Analysis 7.4; Analysis 7.5; Analysis 7.6; Analysis 8.1; Analysis 8.2; Analysis 8.3; Analysis 8.4; Analysis 8.5; and Analysis 8.6. Castel 2012 reported dropouts with reasons, but without reporting whether they were associated with AEs. Monticone 2016 and Monticone 2017 reported increase in pain in both conditions.

We downgraded all sensitivity analyses three times to very low quality; we downgraded outcomes twice for serious inconsistency (high heterogeneity) and once for serious imprecision (wide CIs). Neither the studies themselves nor correspondence with the first author revealed major differences from other studies in intervention content or process, populations, or other features that could account for outcomes which were so much better than those of other studies. Had these studies been included in the 12 analyses, they would have inflated all 12 estimates, with a mean additional SMD of 0.18 (range 0.06 - 0.47) (see Table 1).

#### **Heterogeneity inspection**

We did not undertake the sensitivity analyses by size of trial that we had planned because of low range of variability. In the three analyses of reasonable size that had high heterogeneity ( $I^2 > 50\%$ ), we undertook further exploratory analyses. By visual inspection, we removed the outliers to test for their influence on the overall effect. In Analysis 1.5, heterogeneity of 53% was reduced to 35% by excluding the outlier (Thieme 2006), but results were essentially unchanged. In Analysis 2.2, heterogeneity of 61% was reduced to 54% by the removal of one positive outlier (Williams 1996), but results were essentially unchanged. In Analysis 2.5, removal of the single study (Van Koulil 2010) reduced heterogeneity from 57% to 35%, without affecting the overall result (SMD -0.17 (95% CI -0.30 to -0.03)). Disability analyses in general had higher I<sup>2</sup> values than did pain or distress, and that may be in part attributable to greater diversity in the content of disability scales than in pain and distress scales.

We did not investigate the high heterogeneity in Analysis 3.4; Analysis 3.5; Analysis 3.6; Analysis 4.1; Analysis 4.2; Analysis 4.3; Analysis 4.5; Analysis 4.6; Analysis 5.1; Analysis 5.2; Analysis 5.3; Analysis 5.4; Analysis 5.5; Analysis 5.6; Analysis 6.1; Analysis 6.2; or Analysis 6.3 because all had five or fewer studies in them.

#### DISCUSSION

#### Summary of main results

We included 75 studies in this update (41 new studies; 9401 participants completing treatment). The participants had a range of chronic pain conditions, including fibromyalgia, chronic low back pain, rheumatoid arthritis, osteoarthritis, and TMD, and some trials included a mix of chronic pain conditions. There were more females than males included in trials, and the average age of all participants was 50 years. Most trials delivered CBT, but a minority of studies delivered BT, ACT, or other types of therapies. About half the studies included an active comparison and the remainder a waiting list or TAU control.

We found 59 studies with a CBT arm of treatment. Eight provided no data, and we excluded a further four from the main analyses due to their being extreme outliers. We did include them in sensitivity analyses. Considering the evidence from the 47 studies in the main analyses (5807 participants at the end of treatment), CBT had small or very small benefits over AC for reducing pain at the end of treatment but not at follow-up, for disability both at the end of treatment and at follow-up, and for distress only at follow-up. CBT also showed small benefit over TAU for reducing pain and distress, both at the end of treatment and at follow-up, and for disability only at the end of treatment but not at follow-up. We attempted to translate SMD data into changes on widely used scales (Guyatt 2013), but we were unable to apply any of the methods without introducing further bias because of the variety of scales and wide range of baseline scores. We judged evidence at the end of treatment to be primarily of moderate quality for comparisons with AC or TAU at both time-points. Disability outcomes at followup when compared to AC, and for both time-points when compared to TAU were downgraded to low-quality.

We found 13 studies that delivered BT. We used data from eight studies in analyses (716 participants at the end of treatment). Two studies showed no difference between treatment and AC or TAU for any outcome. BT showed a benefit over AC for disability and distress at follow-up. Behavioural interventions were investigated by a small number of trials representing diverse treatments. Three trials used operant interventions, which have become less widely used (Thieme 2003; Thieme 2006; Turner 1988), but others used graded activity (Geraets 2005; Jensen 2001; Nicassio 1997; Sharpe 2012), and biofeedback (Mishra 2000), both currently widely used in clinical practice. We judged the evidence quality to be very low



for all outcomes when compared to AC, ranging from moderate to very low quality when compared to TAU.

We found six studies that delivered ACT and we used data from all six in analyses (650 participants at the end of treatment). Compared to AC, ACT showed no difference in effect for reducing pain or distress either at the end of treatment or at follow-up, and no difference in effect on disability at the end of treatment. Two studies indicate that ACT reduced disability at follow-up, but we are cautious of these findings due to the small number of participants included. We judged the evidence quality as very low. Compared to TAU, ACT showed no difference in effect for reducing pain, disability or distress at the end of treatment. There are insufficient data on any longer term outcomes. All evidence is of very low quality, meaning that we remain uncertain about the estimates of effect.

There were four other studies, one each of "emotional disclosure," "emotional awareness and expression," "psychodynamic therapy" and "short term dynamic psychotherapy," which were reported narratively.

Most studies reported on all three pain-related outcomes. Overall, the risk of bias was unclear or high, particularly for attrition bias, selective reporting bias, and for treatment expectations. There were insufficient data on AEs of any psychological treatment to allow comparative analyses, meaning that we remain uncertain on whether psychological interventions are associated with any harms.

# Overall completeness and applicability of evidence

Most trials included adults, with a mean age of 50. All trials were undertaken in high-income industrialised economies with access to psychological services. Commonly excluded from trials were patients reporting psychiatric co-morbidities.

We know little about forms of psychological intervention other than CBT, despite their popularity. Further, although the goals of psychological interventions are typically to improve the longterm management of pain and its consequences, we have fewer data on long-term outcomes than we do on short-term outcomes immediately after treatment. Adverse event reporting was rare so we remain uncertain about the safety or tolerability of psychological interventions.

# **Quality of the evidence**

The quality of evidence ranged between moderate and very low, indicating serious limitations to study quality, indirectness, or imprecision (small number of participants or wide Cls). We downgraded outcomes once to moderate for 11 outcomes if we only had concerns about limitations to study quality. CBT outcomes were predominantly judged as moderate quality, BT outcomes were judged to be of moderate to very low-quality, and ACT outcomes were all judged as of very low-quality. meaning that further research is very likely to have an important impact on our confidence in the estimate of effect, likely changing that estimate, or that we are very uncertain about the estimate of effect. Given a broad mixture of outcome metrics within each domain, and considerable heterogeneity at baseline, we were unable to make any meaningful translation of effect sizes into clinically interpretable changes.

#### Potential biases in the review process

Because this is the second update of this review with the original protocol published in 2008, we decided (*a priori*) to publish an updated protocol to control for *post hoc* decision-making (Williams 2018). We followed this protocol when selecting studies and treatment arms for entry into analyses, and for assessing risk of bias.

We think it is unlikely that we have missed any RCTs. We searched three databases for RCTs of psychological therapies, as well as trial registries, reference lists, and citations of included studies. Authors or co-authors of trials included in this review did not extract data from such trials or judge them for risk of bias. We have attempted to minimise all biases when updating this review.

We excluded studies without random allocation of participants to comparative treatments, so did not include any non-randomised, or within-subject randomisation studies. We were unable to undertake analysis at the level of the individual patient (Moore 2010; Moore 2018), and did not focus on individual study-determined primary outcomes but on our *a priori*-determined outcomes, taken from the published reports and not from any unpublished trial study report (e.g. trial registration or grant funder report). We did not compare the effectiveness of any one form of psychological intervention with any other, directly or indirectly.

For the 41 additional trials included in this update, 20 had missing data. We requested data from all 20 and received data from 15.

We excluded four studies from the analyses because their data were statistical outliers in terms of efficacy or trial performance, or both. We wrote to the authors for comment on our proposed strategy of exclusion from the main findings. We received no answer from one (Castel 2012), and no satisfactory explanation was given for the anomalous sizes of outcome and completeness of follow-up data in the remaining three (Monticone 2013; Monticone 2016; Monticone 2017). We included the data and their effects on the estimates in sensitivity analyses.

# Agreements and disagreements with other studies or reviews

The conclusions of this update are broadly in line with the conclusions of the previous version (Williams 2012), although over 50% of the studies in this update are new. The results are similar to those for children and adolescents (Fisher 2018), although in that review around half the trials were for children with headache. There are Cochrane reviews of psychological treatments for both adults and children delivered remotely by a therapist using electronic communication technology (Eccleston 2014; Fisher 2019). Again, the findings are broadly similar. There is low- to moderate-quality evidence for the efficacy of CBT in some immediate outcomes, but rarely in follow-up.

There are many non-Cochrane systematic and narrative reviews, some with meta-analyses. An overview review is out of scope here. It is worth noting that non-Cochrane reviews are often more permissive in allowing non-randomised or underpowered studies to be included. For CBT, the findings are similar to those in high quality reviews. For example, Bernady 2010 used Cochrane methods including GRADE in a review of psychological interventions for adults with fibromyalgia, including 29 RCTs. This agreement extends to CBT in rheumatoid arthritis (Prothero 2018).



There is one attempt at network meta-analysis comparing CBT with a mindfulness protocol (Khoo 2018) which found too few direct comparisons to be able to comment. Although largely unsuccessful, it returned effects for CBT versus control similar to those reported here.

For BT, our findings differ from other reviews. For example, a recent non-Cochrane review of biofeedback in chronic back pain included 21 studies (none included in this review); the authors did not exclude non-randomised or non-inferiority studies; they calculated effects of treatment; and they had no inclusion criteria based on size of trial or the credibility of the therapy content (Sielski 2017). They reported very positive conclusions about its efficacy in reducing disability, depression, and in improving coping in the short and long term.

A review of graded activity and graded exposure included 13 studies, and found small positive effects of graded activity over control in the short term (Villanueva 2016). Eleven of the studies included in this review did not meet our inclusion criteria due to small size and/or lack of credible psychological content.

For ACT, the finding of no evidence of efficacy or safety is at odds with several non-Cochrane reviews. Veehof 2011 combined 22 studies of ACT and mindfulness-based meditation, including nonrandomised trials, and reported ACT to be "promising." In 2016, they updated this to 25 studies, all RCTs, and concluded "...that individuals with pain, in general, respond rather well to acceptanceand mindfulness-based interventions and that beneficial effects are retained after treatment" (Veehof 2016). Twenty-two of the studies included in that review did not meet our inclusion criteria. Twelve of the 25 are ACT studies. Nine of the 12 are not included here, seven because of small size, one because it was not delivered face-to-face, and one because it had no suitable control. One 2017 review included 11 RCTs (Hughes 2017). Their primary outcomes were acceptance of pain, quality of life and functioning. Their conclusions were for a positive effect of ACT on acceptance of pain and on functioning. Eight of the 11 are not included here, five because of small size, two because they were not delivered face-toface, and one because it was a non-inferiority trial. A different 2017 review included 10 studies, had no accessible protocol, attempted no meta-analysis and simply reported on investigator-chosen endpoints (Simpson 2017). Their conclusions were positive for an effect on pain acceptance. Seven of the 10 were not included here, four because of small size, two because they were not delivered face-to-face, and one because it was a non-inferiority trial.

# AUTHORS' CONCLUSIONS

# **Implications for practice**

# For adults with chronic pain (excluding headache and migraine)

We have reasonable certainty from a large evidence base that cognitive behavioural therapy (CBT) can improve patient-relevant outcomes for some adults with chronic pain, reducing pain and disability and improving distress. These findings were immediately after treatment and at follow-up, when compared to active control (AC) or treatment as usual (TAU). The evidence overall is for small or very small beneficial effects. There is no evidence of a difference between behavioural therapy (BT) and control, or acceptance and commitment therapy (ACT) and control, for most outcomes, and the quality of the evidence for these treatments is mostly low or very low. There are other psychological treatments being investigated and offered but there is no evidence to support or refute claims made about their efficacy. We are not able to determine the safety of the treatments as adverse event reporting was low.

# For clinicians

We have sufficient evidence to conclude that CBT has small beneficial effects for the management of chronic pain, although we have insufficient evidence on adverse effects. There is experimental development in other treatments such as ACT, emotional expression, and psychodynamic psychotherapy, but the evidence is insubstantial on either benefits or adverse effects.

#### For policy-makers

For those commissioning psychologically-based interventions for chronic pain in adults, or including such interventions in policy determinations, it is important to recognise that not all psychological treatments are the same. There is variety in the content, delivery, and clinical intentions of treatments, depending on their theoretical provenance. Interventions aim to reduce distress and disability, with or without a reduction in pain. The largest body of evidence we have supports the use, by trained psychologists, of CBT to produce benefits immediately after treatment and at follow-up of at least six months, rather than providing no treatment. The evidence is sufficient (i.e. large and of moderate quality) and unlikely to change with future studies. The overall effects are small or very small, meaning that the population benefit may be large, but more work is needed to identify which patients will individually benefit. There is development in other treatments such as ACT, emotional expression, and psychodynamic psychotherapy, but these remain experimental and monitoring of positive and negative outcomes is advisable.

# For funders of interventions

The evidence supports continuing to provide CBT for chronic pain, delivered by trained psychologists. There are no data here on health care reduction but an extension of the previous systematic review and meta-analysis showed fewer consultations and interventions after psychologically-based treatment (Pike 2016). Other psychological treatments, ACT, BT, and psychodynamic psychotherapy, should be monitored for the primary outcomes analysed here - pain, disability, distress, and adverse effects - and additionally, for health care use after intervention.

# **Implications for research**

# **General implications**

Given the quality of evidence, and the number of trials of CBT, there is no imperative for further randomised controlled trials (RCTs) of standard CBT. Funding should not be allocated to small trials investigating the efficacy of CBT in people with chronic pain, regardless of condition (Ioannidis 2005), since there is a high risk of research waste (Glasziou 2018). Funders should instead focus efforts on investing in large, multi-centre studies investigating different types of psychological therapies for people with chronic pain, including extension of established CBT methods for those with psychiatric co-morbidities, mild cognitive deficits or learning disabilities, opioid overuse, and those otherwise under-represented in populations studied. All trials should make

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individual patient data available to enable individual patient analysis and to allow data pooling to identify sources of variance, since some may suggest ways to maximise treatment benefits. There is extensive interest and pre-clinical study in behavioural treatment content but its translation into clinical studies has been small scale. There is much enthusiasm for ACT as shown in non-Cochrane reviews which include many small trials, and which report beneficial outcomes, but there is no high quality evidence to support such findings. High quality, adequately powered trials are needed, preferably multi-centre and run by investigators with equipoise. There is a need for better translation of discovery research in experimental psychology into clinical development to guide therapy content and delivery, and single case methods may be particularly appropriate here (Morley 2017). There is also a need for high quality trials in novel treatments for which there is insufficient evidence: behavioural interventions such as graded activity and exposure, psychodynamic psychotherapy, and emotion focused psychotherapy.

A substantial minority of studies recruited volunteer participants from the community, with self-reported chronic pain, rather than from clinical populations. While not denying the widespread extent of chronic pain and related disability in the community, baseline scores tended to be low on clinical scales such as for disability and distress, with possible floor effects for change. Separate analysis of clinical and community populations would be worthwhile in a future update. Many trials claim to deliver CBT or other psychological interventions, but without evidence that the treatment was authentic. Here we have used the level of training of therapists delivering it as some guarantee of internal validity but, where therapists are untrained or minimally trained, and treatment content and process are not independently validated by expert observers, there can be no assumption of benefit until demonstrated.

# **Design implications**

A good study design will have: a clear rationale for the treatment that hypothesises how the intervention is thought to work, and how therapy content, described in detail (Hoffmann 2014), might affect the outcomes of interest (Montgomery 2018), and for the choice of comparator; a protocol with power analysis; prespecified outcomes, including adverse effects, and justification for the choice of measurement instruments; adequate power with sufficient participants to allow for attrition over the trial and follow-up periods and to detect clinically meaningful differences in the selected outcomes. Standard corrections for known biases should be made, and triallists should aim for equipoise and independence from therapist allegiance to the treatment delivered.

#### **Measurement implications**

Use of standard measures would improve comparability across studies. Many studies adopt the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) criteria (Dworkin 2005), but there remains a plethora of heterogeneous measurement tools for subjective experiences, with varied content within domains, and few behavioural measures supplementing self-report. It is a particular problem of some experimental therapies that the primary outcome is a psychological abstraction that characterises presumed process rather than outcome (such as 'acceptance'); these abstractions are variably understood or misunderstood by patients (Biguet 2016). They are also hard to translate into metrics of clinical benefits (Morley 2008). Additionally, people with chronic pain identify a far wider range of outcomes than are conventionally assessed (Beale 2011), including patient-reported experience scales (PREMs). Assessment of treatment benefits in terms of reduced costs, in health and social care, and incurred by patients, is generally lacking. Although their identification and standardised assessment is a high priority, adverse effects are poorly assessed across interventions (Palermo 2020). Adverse effects including worsening of distress and other reasons for dropout.

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\* Indicates the major publication for the study

# CHARACTERISTICS OF STUDIES

# **Characteristics of included studies** [ordered by study ID]

## Alaranta 1994

Study characteristics			
Methods	RCT; 2 arms; assessed pretreatment, 3 months follow-up, 1 year follow-up		
Participants	3 month follow-up n = 286		
	Start of treatment n = 293		
	Sex: 160 F, 133 M		
	Mean age = 40.5 (SD 4.5)		
	Source = patients referred for inpatient rehabilitation		
	Diagnosis = chronic low back pain		
	Mean years of pain = not given (minimum 6 months)		
Interventions	"progressive intervention of intensive physical training and psychosocial activation AKSELI"		
	"control: less intensive physical training and passive physical therapies"		
Outcomes	Primary pain outcome: none		
	Primary disability outcome: none		
	Primary distress outcome: BDI		
	Lumbar flexion-extension		
	Lateral flexion		
	Trunk rotation		
	Hamstring tightness		
	Number of sit-ups		
	Number of arch-ups		
	Static strength of back muscles		
	Number of squats		
	Million index of pain and disability: mean of 14 items rated 0 to 100		
	Low back pain capacity 1 to 3		
	Leisure activities physical intensity 0 to 10		
	Number of visits to doctors (12-month follow-up)		
	Number of physical therapy outpatient visits (12-month follow-up)		
	WHO occupational handicap 0 to 5		
	Sick days		
	Beck Depression Inventory		
	Symptom Check List		



Alaranta 1994 (Continued)	
	Multidimensional Health Locus of Control
	Social Adjustment Scale
	Karolinska Scales of Personality
Notes	Excluded from 2009 review for marginal psychological content; included in 2012 update
	No data provided
	Funding statement: None included in paper
	Conflict of interest statement: None included in paper

Risk of bias

Authors' judgement	Support for judgement
Unclear risk	Method not described
High risk	No information but post-randomisation exclusion of participants "not fit" for intervention group
High risk	Self-report and examination by psychiatrist and physiotherapist at baseline and follow-up. No statement about blinding.
Low risk	Attrition < 10%, method for dealing with missing data not described
High risk	Trial not pre-registered. Many outcomes not reported in results section
Unclear risk	Not assessed
	Unclear risk High risk Low risk High risk

### Alda 2011

Study characteristics	
Methods	RCT; 3 arms; assessed pretreatment, post-treatment, 1-, 3-, 6-months
Participants	Start of treatment n = 169 (168 started treatment)
	Post-treatment n = 162
	Sex: 159 F, 9 M
	Mean age = 46.8 (SD 6.5)
	Source = 41 primary health care centres in Spain
	Diagnosis = fibromyalgia
	Mean years of pain = 11.9 (SD 5)
Interventions	CBT "Cognitive-behaviour therapy"



Alda 2011 (Continued)			
	RPT "Recommended pharmacological treatment" pregabalin & duloxetine		
	TAU "Treatment as usual" by GP using guide to treatment of fibromyalgia		
Outcomes	Primary pain outcome: Pain Visual Analogue Scale		
	Primary disability outcome: Fibromyalgia Impact Questionnaire		
	Primary distress outcome: Hamilton Rating Scale for Depression		
	Pain catastrophising scale PCS total (primary outcome)		
	MINI psychiatric interview		
	Hamilton Rating Scale for Depression		
	Hamilton Anxiety Rating Scale		
	Pain Visual Analogue Scale		
	Chronic Pain Acceptance Questionnaire		
	Fibromyalgia Impact Questionnaire (global function)		
	EuroQoL-5D questionnaire (quality of life)		
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
	Trial registered: ISRCTN10804772		
	Funding statement: Carlos III Health Institute of the Spanish Ministry of Health and Consumption (ETES PI07/90959).		
	Conflict of interest statement: "The authors declare that they have no competing interests."		

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Each patient was assigned to one of the three groups by a computer-generat- ed random number sequence" stratified by depression
Allocation concealment (selection bias)	Low risk	Allocation sequence generated by a member of the research group not in- volved in the study. Patients automatically assigned to a group according to the random allocation sequence.
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The study personnel who carried out the measurements were kept blinded to which treatment each patient received"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16% attrition: however, authors used a LOCF analysis
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (ISRCTN10804772), all outcomes reported from protocol
Treatment expectations	Unclear risk	Not assessed



### Alonso-Fernandez 2016

Study characteristics			
Methods	RCT; 2 arms; assessed p	pretreatment, post-treatment	
Participants	Post-treatment n = 53		
	Start of treatment n = 1	01	
	Sex: 79 F, 22 M		
	Mean age (minimum 65	5) = 83 (SD 6.8)	
	Source = nursing home	s	
	Diagnosis = chronic mu	isculoskeletal pain	
	Mean years of pain = 23	3.3 (SD 20.6)	
Interventions	ACT "ACT-selective opti	imization with compensation" 18 hours	
	MS minimal support "L tion	ess intensive physical training and passive physical therapies" plus brief educa-	
Outcomes	Primary pain outcome	e: Brief Pain Inventory pain severity	
	Primary disability outcome: Brief Pain Inventory pain interference		
	Primary distress outcome: Geriatric Depression Scale		
	Brief Pain Inventory		
	Geriatric Depression Scale		
	Pain Anxiety Symptoms Scale-Short form PASS-20		
	Pain Catastrophizing Scale		
	Selection, Optimization, and Compensation questionnaire		
	Chronic Pain Acceptance Questionnaire		
Notes	ACT vs active control: a	inalyses 3.1, 3.2, 3.3	
	Funding statement: "This study was supported by a grant from the MAPFRE Foundation. Primiti- vo de Vega. The collaboration of Andrés Losada in this project has been supported by the Grant PSI2012-31293, funded by the Spanish Ministry of Economy and Competitiveness and the collaboration of José Luis Gonzalez in this project has been supported by the Grants PSI2010-21888, funded by the Spanish Ministry of Science and Innovation, and URJC-CM- 2010-CSH-5530, funded by the Community of Madrid and the Rey Juan Carlos University."		
	Conflict of interest stat	ement: None included in paper	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Participants were randomized to each treatment condition (ACT-SOC or MS) using a randomized, computer-generated list."	
Allocation concealment (selection bias)	Unclear risk	No description	

### Alonso-Fernandez 2016 (Continued)

Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessors were psychologists blind to study hypotheses and allocation of par- ticipants
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10% and completer analysis performed
Selective reporting (re- porting bias)	Unclear risk	No protocol registered
Treatment expectations	Unclear risk	Not assessed

### Altmaier 1992

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months
Participants	End of treatment n = 42
	Start of treatment n = 45
	Sex: 12 F, 33 M
	Mean age = 39.9 (SD 8.9)
	Source = pain and rehabilitation clinic
	Diagnosis = chronic low back pain
	Mean years of pain = not given
Interventions	"Psychology based programme: multicomponent CBT"
	"Standard inpatient rehabilitation"
Outcomes	Primary pain outcome: MPQ PRI
	Primary disability outcome: WHYMPI pain interference
	Primary distress outcome: WHYMPI distress Primary aerobic impairment
	Self efficacy
	West Haven Yale Multidimensional Pain Inventory (WHYMPI) self control
	WHYMPI pain interference
	WHYMPI mood
	Disability
	Melzack Pain Questionnaire Pain Response Index (MPQ PRI)
Notes	Funding statement: NIH for Handicapped Research (G008435055)
	Conflict of interest statement: None included in paper



Altmaier 1992 (Continued)

### CBT vs TAU, post-treatment and follow-up: analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

**Risk of bias** 

Authors' judgement	Support for judgement
Unclear risk	Abstract: "Forty-five low back pain patients were randomly assigned"; method not described
Unclear risk	Not reported
Unclear risk	Not reported
Low risk	Attrition < 10%, but method for dealing with missing data not described
Unclear risk	Trial not pre-registered
Unclear risk	Not assessed
	Unclear risk Unclear risk Unclear risk Low risk Unclear risk

# Barsky 2010

Study characteristics	
Methods	RCT; 3 arms; assessed pretreatment, post-treatment, 6-, and 12-months
Participants	Post-treatment n = 133 at 6 months
	Start of treatment n = 168
	Sex: 146 F, 22 M
	Mean age = 53.4 (SD 12.9)
	Source = hospital, public advertisements
	Diagnosis = rheumatoid arthritis
	Mean years of pain = 13.5 (SD 11.5)
Interventions	CBT - Cognitive behavioural therapy
	RR - Relaxation response training
	AE - Arthritis eduction
Outcomes	Primary pain outcome: Rheumatoid Arthritis Symptom Questionnaire (RASQ) VAS 1-10
	Primary disability outcome: Arthritis Impact Measurement Scale (AIMS-2) Mobility
	Primary distress outcome: Rand Mental Health Inventory (Depression)
	Rheumatoid Arthritis Symptom Questionnaire (RASQ)

Barsky 2010 (Continued)	
	Arthritis Impact Measurement Scale (AIMS-2)
	Erythrocyte sedimentation rate (ESR)
	Standardised physician ratings of joint swelling to index disease severity and activity
	Medications
	Rand Mental Health Inventory
Notes	No data provided
	Funding statement: Supported by research grant R01 AR 4701401 from the National Institute of Arthritis & Musculoskeletal and Skin Diseases.
	Conflict of interests: None described.

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Once five subjects were accrued, this group was randomly assigned by com- puter to one of the three treatment modalities"
Allocation concealment (selection bias)	High risk	No description of allocation. However, this statement was included in the text suggesting that the latter participants had unequal chance of being ran- domised to treatment conditions. "However, after accruing 127 patients, un- equal numbers of patients across the treatment arms led us to an unbalanced randomization for the remaining 41 patients in order to restore balance."
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Data were gathered by research assistants blind to treatment modality, and the therapists had no role in data collection."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition > 10%. LOCF analyses used.
Selective reporting (re- porting bias)	Unclear risk	Protocol registered (NCT00056667). Some questionnaires registered in proto- col not included in manuscript.
Treatment expectations	Unclear risk	Not assessed.

Basler 1997		
Study characteristic	cs	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months	
Participants	End of treatment n = 76	
	Start of treatment n = 94	
	Sex: 57 F, 19 M	
	Mean age = 49.3 (SD 9.7)	
	Source = pain or rehabilitation clinic	



Basler 1997 (Continued)	Diagnosis = chronic low back pain		
	Mean years of pain = 10.8		
Interventions	"CBT added to medical treatment" "Medical treatment"		
Outcomes	Primary pain outcome: Pain Intensity Numerical Rating Scale (0 to 10)		
	Primary disability outcome: disability in physical function from Dusseldorf Disability Scale		
	Primary distress outcome: none		
	Pain Intensity Numerical Rating Scale (0 to 10)		
	Control over pain Numerical Rating Scale (0 to 10)		
	Days per week pain-free		
	Days per week pain medication use		
	Use of cognitive strategies (self-report)		
	Use of avoidance behaviour (self-report)		
	Pleasant activities (self-report)		
	Social support (self-report)		
	Philosophical beliefs (self-report)		
	Catastrophising (bespoke scale)		
	Active coping (bespoke scale)		
	Disability in social relationships from Dusseldorf Disability Scale		
	Disability in social roles from Dusseldorf Disability Scale		
	Disability in physical function from Dusseldorf Disability Scale		
	Disability in mental performance from Dusseldorf Disability Scale		
	Disability in physical performance from Dusseldorf Disability Scale		
Notes	Funding statement: German Ministry of Research and Technology (No 0701508) and Fulbright Commis- sion Germany, Category LR		
	Conflict of interest statement: None included in paper		
	CBT versus TAU, post-treatment: analyses 2.1, 2.2		
Risk of bias			
Bias	Authors' judgement Support for judgement		
Random sequence genera- tion (selection bias)	Unclear risk Method not described		
Allocation concealment (selection bias)	Unclear risk Not reported		



### Basler 1997 (Continued)

Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Completer analyses conducted, attrition > 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Bliokas 2007

Study characteristics	
Methods	RCT; 3 arms; assessed pre-treatment and post-treatment
Participants	End of treatment n = 94
	Start of treatment n = 143
	Sex: 79 F, 64 M
	Mean age = 45.2 (SD 9.2)
	Source = referrals to Pain Management Service after medical treatment completed
	Diagnosis = chronic non-cancer pain
	Mean years of pain = median 4.0
Interventions	"Graded exposure in vivo and outpatient multidisciplinary chronic pain management group program"
	"Outpatient multidisciplinary chronic pain management group program"
	"Waiting list control"
Outcomes	Primary pain outcome: Pain VAS
	Primary disability outcome: Pain Disability Index
	Primary distress outcome: DASS depression
	Pain VAS
	Tampa Scale for Kinesiophobia: fear of movement/re/injury
	Pain Self-Efficacy Questionnaire (PSEQ)
	Pain Disability Index (PDI)
	Depression, Anxiety & Stress Scale (DASS): depression and anxiety scores only
	Activity level: performance over 2 weeks of 10 usually-avoided activities
	6-minute walk test
Notes	Funding statement: Supported by a NSW Motor Accidents Authority (Australia) research grant.



Bliokas 2007 (Continued)

Conflict of interest statement: None included in paper

Chronic pain management programme with graded exposure vs waiting list control

December 2009 search

Data obtained from author: analyses 2.1, 2.2, 2.3

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"A random numbers generation of the numbers 1 to 3 was produced at the commencement of the study, with each number corresponding to the 3 experimental conditions"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	High risk	Examination by physiotherapist and self report: no blinding reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%: method of dealing with missing data not described
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Buckelew 1998

Study characteristics		
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment, 3 months, 1 year, 2 years	
Participants	End of treatment n = 109	
	Start of treatment n = 119	
	Sex: 108 F, 11 M	
	Mean age = 44 (SD 10)	
	Source = mainly community	
	Diagnosis = fibromyalgia	
	Mean years of pain = 11.5	
Interventions	"Biofeedback + relaxation + exercise"	
	"Biofeedback + relaxation"	
	"Exercise"	
	"Education attentional control"	



Buckelew 1998 (Continued)			
Outcomes	<ul> <li>Primary pain outcome: no data available</li> <li>Primary disability outcome: no data available</li> <li>Primary distress outcome: no data available</li> <li>Arthritis Impact Measurement Scale: Physical Activity subscale (AIMS)</li> <li>Symptom Checklist (SCL-90R) distress</li> <li>Center for Epidemiologic Studies Depression Scale (CES-D)</li> </ul>		
	Arthritis Self-Efficacy S	cale	
	Sleep rating 0 to 12		
	Tender Point Index		
	Myalgic score		
	Physician's VAS rating of disease severity		
	Keefe & Block Pain Behaviour: observation		
Notes	otes Funding statement: NIAMS (DHHS 1-R29-AR39481) and National Institute on Disability and Retion Research (H133B80075) Conflict of interest statement: None included in paper No data provided		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	Method not described	
Allocation concealment	Unclear risk	Not reported	

Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Subjects examined by physician unaware of treatment conditions and with no other contact with subjects
Incomplete outcome data	Low risk	Attrition < 10%; method to deal with missing data not described

(attrition bias) All outcomes			
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered	
Treatment expectations	Unclear risk	Not assessed	

### Carson 2006

(selection bias)

**Study characteristics** 

Methods

RCT; 4 arms; assessed at pretreatment, post-treatment, 6 and 18 months



Carson 2006 (Continued)			
Participants	Post-treatment n = 128		
	Start of treatment n = 167		
	Sex: 137 F, 30 M		
	Mean age = 55.8 (SD 13.2)		
	Source = rheumatology clinic		
	Diagnosis = rheumatoid arthritis		
	Mean years of pain = not stated		
Interventions	PCST "Conventional pain coping skills training"		
	PCST/MT "Coping skills training + maintenance"		
	AE "Arthritis education"		
	SC "Usual care"		
Outcomes	Primary pain outcome: Joint pain from Rapid Assessment of Disease Activity in Rheumatology		
	Primary disability outcome: None		
	<b>Primary disability outcome:</b> None <b>Primary distress outcome:</b> Negative mood from Profile of Mood States-B (abbreviated version)		
	Primary distress outcome: Negative mood from Profile of Mood States-B (abbreviated version)		
	<b>Primary distress outcome:</b> Negative mood from Profile of Mood States-B (abbreviated version) Rapid Assessment of Disease Activity in Rheumatology joint pain, 0-3 for each of 20 joints, summed		
	<b>Primary distress outcome:</b> Negative mood from Profile of Mood States-B (abbreviated version) Rapid Assessment of Disease Activity in Rheumatology joint pain, 0-3 for each of 20 joints, summed Daily Coping Inventory		
Notes	<ul> <li>Primary distress outcome: Negative mood from Profile of Mood States-B (abbreviated version)</li> <li>Rapid Assessment of Disease Activity in Rheumatology joint pain, 0-3 for each of 20 joints, summed</li> <li>Daily Coping Inventory</li> <li>2 items from Coping Strategies Questionnaire on self-efficacy for coping</li> </ul>		
Notes	<ul> <li>Primary distress outcome: Negative mood from Profile of Mood States-B (abbreviated version)</li> <li>Rapid Assessment of Disease Activity in Rheumatology joint pain, 0-3 for each of 20 joints, summed</li> <li>Daily Coping Inventory</li> <li>2 items from Coping Strategies Questionnaire on self-efficacy for coping</li> <li>Profile of Mood States-B (abbreviated version), positive and negative mood scores</li> </ul>		
Notes	<ul> <li>Primary distress outcome: Negative mood from Profile of Mood States-B (abbreviated version)</li> <li>Rapid Assessment of Disease Activity in Rheumatology joint pain, 0-3 for each of 20 joints, summed</li> <li>Daily Coping Inventory</li> <li>2 items from Coping Strategies Questionnaire on self-efficacy for coping</li> <li>Profile of Mood States-B (abbreviated version), positive and negative mood scores</li> <li>CBT vs AC, post-treatment: 1.1, 1.3</li> </ul>		

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Assignments were generated by an individual not involved in the study, using a random number table"
Allocation concealment (selection bias)	Low risk	"Assignments were concealed in envelopes that were not opened until the pa- tient was randomized"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"All study personnel involved in data collection were blind with respect to each participant's treatment group assignment"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	LOCF analyses used; attrition > 10%



# Carson 2006 (Continued)

Selective reporting (re-Unclear risk Trial n porting bias)

Trial not pre-registered

Treatment expectations Unclear risk

Not assessed

### Castel 2012

Study characteristics			
Methods	RCT; 3 arms; assessed pretreatment, post-treatment, 3-, 6-months		
Participants	Post-treatment n = 87		
	Start of treatment n = 93		
	Sex: 4 F, 119 M (screening)		
	Mean age = 49.6 (SD 6.8)		
	Source = Hospital		
	Diagnosis = Fibromyalgia		
	Mean years of pain = 12.6 (SD 8.4)		
Interventions	CBT "Standard pharmacological treatment with CBT"		
	CBT+hypnosis "Standard pharmacological treatment with CBT + hypnosis"		
	TAU "Standard pharmacological care"		
Outcomes	Primary pain outcome: Numerical Rating Scale		
	Primary disability outcome: Fibromyalgia Impact Questionnaire		
	Primary distress outcome: Hospital Anxiety and Depression Scale		
	Numeric Rating Scale		
	Subscale of Catastrophizing From the Coping Strategies Questionnaire		
	Hospital Anxiety and Depression Scale total score		
	Fibromyalgia Impact Questionnaire		
	Medical Outcomes Study Sleep Scale		
Notes	CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
	Funding statement: None included in paper Conflict of interest statement: "There are no conflicts of interest associated with this study"		
Risk of bias			
Bias	Authors' judgement Support for judgement		
Random sequence genera- tion (selection bias)	Unclear risk No details of method used		



### Castel 2012 (Continued)

Allocation concealment (selection bias)	Unclear risk	Unclear how participants allocated
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"All outcome measures were administered by a psychologist who was blinded to the participants' group assignment"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	LOFC analyses conducted; < 10% attrition
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Castel 2013

Study characteristics			
Methods	RCT; 2 arms; assessment pre-treatment, post-treatment, 3, 6 and 12 months follow-up		
Participants	End of treatment n = 142		
	Start of treatment n = 155		
	Sex: 155 F, 0 M		
	Mean age = 49 (SD 7)		
	Source = rheumatology clinic		
	Diagnosis = fibromyalgia		
	Mean years of pain = 7.7 (s.d. 8.9)		
Interventions	CBT: Multidisciplinary treatment + usual drug treatment		
	Control: usual drug treatment		
Outcomes	Primary pain outcome: NRS 0-10		
	Primary disability outcome: Fibromyalgia Impact Questionnaire (FIQ)		
	Primary distress outcome: HADS total		
	Catastrophizing subscale of Coping Strategies Questionnaire (CSQ)		
	Quality of life Dartmouth COOP/WONCA		
	Sleep subscale from MOS		
Notes	CBT vs TAU, post-treatment and 12-month follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
	Funding statement "Supported by the Foundation Marató TV3 (grant 070910)."		
	Conflict of interest: no statement		

# **Risk of bias**

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### Castel 2013 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"randomly assigned in 1-1 ratio in blocks of 32 according to a random number table"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Evaluators blinded to treatment condition
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; last observation carried forward
Selective reporting (re- porting bias)	High risk	Health-related QoL assessed but not reported; no protocol
Treatment expectations	Unclear risk	Not reported

### Castro 2012

Study characteristics				
Methods	RCT; 2 arms; assessed pretreatment and post-treatment			
Participants	Post-treatment n = 93			
	Start of treatment n = 95			
	Sex: 83 F, 10 M			
	Mean age = 47.3 (SD 11.2)			
	Source = Pain clinic			
	Diagnosis = Mixed chronic pain			
	Mean years of pain = not possible to calculate from data, but most over 2y.			
Interventions	CBT "Cognitive behavioural therapy"			
	Standard care "Control"			
Outcomes	Primary pain outcome: Visual analogue scale			
	Primary disability outcome: Quality of Life Scale (SF-36), physical limitations			
	Primary distress outcome: Hospital Anxiety and Depression Scale			
	Visual analogue scale			
	Quality of Life Scale (SF-36)			
	Hospital Anxiety and Depression Scale			
Notes	CBT vs TAU, post-treatment: 2.1, 2.2, 2.3			



Castro 2012 (Continued)

Funding statement: None included in paper Conflict of interest statement: "There is no conflict of interest to declare"

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"It was a randomized clinical trial with parallel groups." No description of ran- domisation method
Allocation concealment (selection bias)	Unclear risk	No description
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No description
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10% but no details provided regarding handling of missing data.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

# Chavooshi 2016

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, and 3 months follow-up		
Participants	Post-treatment n = 52		
	Start of treatment n = 63		
	Sex: 19 F, 44 M		
	Mean age = 32.7 (SD 7.0)		
	Source = Not stated		
	Diagnosis = Mixed chronic pain conditions		
	Mean years of pain = 3.24 (SD 0.96)		
Interventions	ISTDP "Intensive short-term dynamic psychotherapy"		
	MBSR "Mindfulness-based stress reduction"		
	TAU "Treatment as usual"		
Outcomes	Primary pain outcome: Numerical Pain Rating Scale		
	Primary disability outcome: None		
	Primary distress outcome: Depression Anxiety Stress Scale 21		
	Numerical Pain Rating Scale		



Chavooshi 2016 (Continued)			
	Emotion Regulation Questionnaire		
	Depression Anxiety Stress Scale DASS 21		
	Mindful Attention Awareness Scale		
	Treatment acceptability		
	Treatment satisfaction		
Notes	Not analysed: "other"		
	Funding statement: None included in paper Conflict of interest statement: None included in paper		

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"63 patients were randomly allocated." Randomisation procedure unclear
Allocation concealment (selection bias)	Unclear risk	Unclear how participants allocated
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No description
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10% and no description of how dropouts handled
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	Treatment expectations assessed: "no difference between treatment groups"

### Cherkin 2014

# **Study characteristics** Methods RCT; 3 arms; assessed pretreatment, post-treatment, 6-, and 12 months Participants Post-treatment n = 305 Start of treatment n = 342 Sex: 224 F, 117 M Mean age = 49.3 (SD 12.3) Source = medical clinic Diagnosis = chronic lower back pain Mean years of pain = none stated CBT "Cognitive behavioural therapy" Interventions Psychological therapies for the management of chronic pain (excluding headache) in adults (Review)

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Cherkin 2014 (Continued)			
. ,	MBSR "Mindfulness-based stress reduction"		
	"Usual care"		
Outcomes	Primary pain outcome: Pain intensity (Graded Chronic Pain Scale)		
	Primary disability outcome: Roland Disability Questionnaire 23 items		
	Primary distress outcome: Patient Health Questionnaire-8 (Depression)		
	Pain bothersomeness 0-10		
	Generalized Anxiety Disorder scale		
	Graded Chronic Pain Scale pain intensity 0-10		
	Patient Global Impression of Change scale		
	Short Form Health Survey (SF-12)		
	Mediator questionnaires		
	Nonreactivity, Observing, Acting with Awareness, and Nonjudging subscales of the Five Facet Mindful- ness Questionnaire short form		
	Chronic Pain Acceptance Questionnaire		
	Patient Self-Efficacy Questionnaire		
	Survey of Pain Attitudes 2-item Control, Disability, and Harm scales		
	Pain Catastrophizing Scale		
	Chronic Pain Coping Inventory 2-item Relaxation scale		
	Activity Pacing scale		
	Adverse events		
Notes	CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
	Trial registration: NCT01467843		
	Funding statement: National Center for Complementary and Integrative Health (NICCIH) of the Nation- al Institutes of Health (NIH) under award number R01AT006226 Conflict of interest statement: "All authors have completed and submitted the ICMJE Form for Disclo- sure of Potential Conflicts of Interest and none were reported"		

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Participants were randomized within these strata in blocks of 3, 6, or 9. The stratified randomization sequence was generated by the study biostatistician using R statistical software"
Allocation concealment (selection bias)	Unclear risk	"sequence was stored in the study recruitment database and concealed from study staff until randomization." Sequence concealed but method not stated
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Trained interviewers, masked to treatment group, collected data by tele- phone at baseline (before randomization) and after randomization at weeks 4 (mid-treatment), 8 (post-treatment), 26 (primary end point), and 52"

### Cherkin 2014 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition > 10% but ITT analysis with imputation of missing values
Selective reporting (re- porting bias)	Low risk	Trial pre-registered and primary outcomes identical in protocol and manu- script (clinicaltrials.gov Identifier: NCT01467843)
Treatment expectations	Low risk	Expectations assessed and are similar at baseline, although group differences not discussed

#### De Souza 2008

# Study characteristics Methods RCT; 2 arms; assessed pre-treatment, post-treatment, 4 months, 12 months Participants End of treatment n = 55 Start of treatment n = 60 Sex: 60 F, 0 M Mean age = 49.6 (SD 7.0) Source = not stated Diagnosis = fibromyalgia Mean years of pain = 12.4 Interventions ISF/EIF "Interactional School of Fibromyalgia" "Control" not described Outcomes Primary pain outcome: MPI pain severity Primary disability outcome: MPI interference with daily activity Primary distress outcome: MPI mood VAS pain (pain diary) MPI pain severity MPI pain interference daily activity MPI control over pain MPI mood MPI family and social support VAS suffering (pain diary) VAS ability to do daily activity (pain diary) Notes Funding statement: "The authors thank the funding agencies Coordination for the Improvement of Higher Education Personnel (Capes) - full doctorate scholarship abroad for JBS - and Canadian Institutes of Health Research (CIHR) and Fonds de Recherche Santé Québec (FRSQ) - SM research funds" Conflict of interest statement: None included in paper



De Souza 2008 (Continued)

December 2009 search

No data provided

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" but method not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Completer analyses conducted as well as ITT analyses; no description of how missing data were handled; attrition < 10%
Selective reporting (re- porting bias)	Low risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Ersek 2008

Study characteristics	s
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6-month follow-up, 12-month follow-up
Participants	End of treatment n = 218
	Start of treatment n = 256
	Sex: 210 F, 46 M
	Mean age = 81.8 (SD 6.5)
	Source = residential retirement facilities
	Diagnosis = pain more than 3 months; average last week > 2/10: mixed sites (largest proportion legs and feet)
	Mean years of pain = not given
Interventions	"pain self-management training group (SMG) intervention"
	"education only control condition"
Outcomes	Primary pain outcome: BPI pain
	Primary disability outcome: RMDQ
	Primary distress outcome: Geriatric Depression Scale Roland & Morris Disability Questionnaire



	CPCI: coping self statements
	CPCI: seeking support
	CPCI: exercise/stretch
	CPCI: task persistence
	CPCI: relaxation
	CPCI: asking for assistance
	CPCI: resting
	Chronic Pain Coping Inventory (CPCI): guarding
	CSQ catastrophising
	Arthritis Self-Efficacy Scale
	Geriatric Depression Scale
	Brief Pain Inventory: interference with activity
Ersek 2008 (Continued)	Brief Pain Inventory: pain

Funding statement: Grant #R01 NR007787 from the National Institute of Nursing Research, National Institutes of Health Conflict of interest statement: None included in paper

CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Randomisation by (retirement) facility, by statistician using random number generator
Allocation concealment (selection bias)	Low risk	By independent statistician
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Completer analysis conducted; attrition > 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (ISRCTN11899548); outcomes in paper match those in pro- tocol
Treatment expectations	Unclear risk	Ν
		ot assessed



### **Evers 2002**

Study characteristics	5	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months follow-up	
Participants	End of treatment n = 59	
	Start of treatment n = 64	
	Sex: 42 F, 17 M	
	Mean age = 54.1 (SD 11.4)	
	Source = rheumatology clinic	
	Diagnosis = rheumatoid arthritis	
	Mean years of pain = 3.1	
Interventions	"Tailor-made CBT"	
	"Treatment as usual"	
Outcomes	Primary pain outcome: IRGL Pain	
	Primary disability outcome: IRGL Functional Disability (Composite Z score)	
	Primary distress outcome: BDI depression	
	Disease Activity	
	Invloed van Reuma op Gezondheid en Leefwijze (IRGL): Functional Disability	
	IRGL: Pain	
	IRGL: Anxiety	
	IRGL: Perceived support	
	Social network	
	Illness Cognitions: Helplessness	
	Illness Cognitions: Acceptance	
	Active Coping with Pain	
	Passive Coping with pain	
	Active Coping with Stress	
	Passive Coping with Stress	
	Fatigue	
	Beck Depression Inventory	
	Negative Mood (ZwartSpooren)	
	Medication compliance	
Notes	Funding statement: "This study was supported by grants from the Dutch Arthritis Association ('Nation- aal Reumafonds')" Conflict of interest statement: None included in paper	



Evers 2002 (Continued)

CBT vs TAU, post-treatment and follow-up: analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"The 64 patients were randomly assigned to one of the two conditions accord- ing to a previously determined pattern of random numbers"
Allocation concealment (selection bias)	Low risk	"previously determined pattern of random numbers"
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	"Joint score ratings were assessed by four rheumatology consultants: two fol- lowed the patients over time, i.e. the same consultant scored patients at three times, at pre-treatment, post-treatment and follow-up assessment. During these visits, patients also received the questionnaires which they were asked to complete at home" Unknown whether consultants were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Completer and ITT analyses using LOCF; attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Ferrando 2012

Study characteristics	5
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, and 9 months follow-up
Participants	Post-treatment n = 59
	Start of treatment n = 72
	Sex: 52 F, 7 M
	Mean age = 39 (SD 15.2)
	Source = Stomatology department
	Diagnosis = temporomandibular disorder
	Mean years of pain = not given
Interventions	CBT "Cognitive behavioural therapy" including hypnosis plus usual care as below
	"Control" - usual care including splints, exercise recommendations, NSAID and/or muscle relaxant drugs
Outcomes	Primary pain outcome: Pain intensity
	Primary disability outcome: Pain interference
	Primary distress outcome: Brief Symptoms Inventory-18
	Number of painful points on pressure



Ferrando 2012 (Continued)				
	Pain frequency			
	Pain intensity (Chronic Pain Grade)			
	MPI pain interference			
	Brief Symptom Inventory 18 emotional distress			
	Self-medication			
	Subjective pain index (McGill Pain Questionnaire)			
	Pain severity MPI			
Notes	CBT vs TAU, post-treatment: 2.1, 2.2, 2.3			
	Funding statement: "The research has been funded by the Spanish Ministry of Science and Technol- ogy (SEJ2009-02440) and the Valencian Regional Government of Industry, University and Science (GV06/373)" Conflict of interest statement: None included in paper			

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"A simple randomization method was used to ensure that each element from the initial sample had an equal probability of being assigned to the experimen- tal or the control group. An external statistical program assigned a number (between 0 and 9,999) to the subject included in the research sample: In this case, when the number was between 0 and 5,549, the patient was assigned to the experimental group, the rest (between 5,550 and 9,999) to the control group, compensating for the expected drop-out rate of 25% in the experimen- tal group"
Allocation concealment (selection bias)	Unclear risk	Treatment allocation not described
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	The two PhD psychologists taking assessments were blind to the conditions of the assessed subjects
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; average scores used to calculate missing data
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

## **Garcia-Palacios 2015**

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment and post-treatment
Participants	Post-treatment n = 59

Garcia-Palacios 2015 (Continue	ed) Start of treatment n = 61		
	Sex: 61 F, 0 M		
	Mean age = 50.5 (SD 9.8)		
	Source = rheumatology clinic		
	Diagnosis = fibromyalgia		
	Mean years of pain = 9.3 (SD 8.2)		
Interventions	CBT with VR, "VR activity management"		
	TAU "Treatment as usual" - rheumatology care		
Outcomes	Primary pain outcome: Brief Pain Inventory		
	Primary disability outcome: Fibromyalgia Impact Questionnaire		
	Primary distress outcome: Beck Depression Inventory		
	Brief Pain Inventory BPI pain		
	Brief Pain Inventory BPI interference		
	Fibromyalgia Impact Questionnaire FIQ		
	Beck Depression Inventory		
	Chronic Pain Coping Inventory		
	Quality of Life Index QLI-Sp		
	Satisfaction and acceptability		
Notes	CBT vs TAU, post-treatment: 2.1, 2.2, 2.3		
	Funding statement: "'Supported in part by Fundació La Marató de TV3 (Ajuts de la Marató de TV3 2006), Barcelona, Spain. Ministerio de Educación y Ciencia, PROYECTOS CONSOLIDER-C (SEJ2006-14301/ PSIC), Madrid, Spain. Fundació Caixa Castelló -Bancaixa (P11B2009-30), Castellon, Spain, and by Gener- alitat Valenciana, Redes de Excelencia ISIC (ISIC/2012/012), Valencia, Spain." Conflict of interest statement: "The authors declare no conflict of interest."		

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Next, using a free software tool named Random Allocation Software 2.0 (http://randomallocation-software.software.informer.com/2.0), they were ran- domly allocated to one of the experimental conditions"
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No description
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition < 10%; "Missing data due to drop out were addressed using last ob- servation carried forward method".



## Garcia-Palacios 2015 (Continued)

Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Geraets 2005

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 1 year		
Participants	End of treatment n = 158		
	Start of treatment n = 176		
	Sex: 109 F, 83 M (at start of treatment)		
	Mean age = 52.5 (SD 12.4)		
	Source = mixed community and volunteer		
	Diagnosis = shoulder pain		
	Mean years of pain = not given		
Interventions	"Graded exercise"		
	"Primary care TAU"		
Outcomes	Primary pain outcome: NRS		
	Primary disability outcome: Shoulder Disability Questionnaire		
	Primary distress outcome: None Shoulder disability questionnaire		
	Shoulder pain		
	Pain intensity NRS		
	Quality of life		
	Fear avoidance		
	Kinesiophobia (2 items)		
	Pain Coping and Cognition List: catastrophising		
	Pain Coping and Cognition List: coping		
	General Practitioner visits		
	Physician visits		
	Physiotherapy visits		
	Number of drug prescriptions		
	Number of days work absence		
	Total cost of health care (€)		



### Geraets 2005 (Continued)

Notes

Funding statement: This study was funded by the Netherlands Organization for Scientific Research (NWOMW, grant number 904-65-901) and by 'De Drie Lichten' Foundation, Hilversum, The Netherlands. Conflict of interest statement: None included in paper

BT versus TAU: analyses 4.1, 4.2, 4.5

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Block randomisation according to random number table
Allocation concealment (selection bias)	Low risk	Random number table generated by person not involved in study; opaque sealed envelopes
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Researchers not involved in randomisation collected data
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Mean imputation was used for missing data; 10% attrition
Selective reporting (re- porting bias)	Low risk	Trial protocol published and outcomes in protocol match those reported in outcome paper
Treatment expectations	Unclear risk	Not assessed

### Glombiewski 2010

Study characteristics		
Methods	RCT; 3 arms: CBT + biofeedback; CBT; waiting list control; assessed post-treatment (WLC assigned to treatment so no WLC at 6-month follow-up)	
Participants	End of treatment: n = 116	
	Start of treatment: n = 128	
	Sex: 77 F, 39 M	
	Mean age: 48.8 (SD 11.7)	
	Source = medical referrals (86%) or response to newspaper advert (14%)	
Diagnosis = chronic back pain		
	Mean years of pain: 8.1 (SD 8.7)	
Interventions	"CBT with biofeedback"	
	"CBT"	
	"waiting list control"	
Outcomes	Primary pain outcome: 0 to 10 NRS pain intensity	



Glombiewski 2010 (Continued)	Primary disability outcome: PDI		
	Primary distress outcome: BDI Pain intensity 0 to 10 NRS		
	Pain average of 4x daily	y diary for 1 week	
	Pain Disability Index		
	Beck Depression Inven	tory	
	Coping Strategies Scale	e from FESV	
	Health-Related Life Sat	tisfaction Scale	
	Global treatment chan	ge	
	Treatment satisfaction		
	(Adverse events noted from pain intensity and global treatment change)		
	Health care use: doctor	r visits for pain	
Notes	Funding statement: None included in paper Conflict of interest statement: None included in paper		
	Combined (CBT + biofeedback and CBT) versus WLC: analyses 2.1, 2.2, 2.3		
	2011 update search		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	Randomisation by random number generation	
Allocation concealment (selection bias)	Unclear risk	"coordinated by the first author" before study	

Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Analyses dealing with incomplete data not described; attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

### Greco 2004

Study characteristics	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6/9 months



Greco 2004 (Continued)			
Participants	End of treatment n = 80		
	Start of treatment n = 92		
	Sex: 87 F, 5 M (at start of treatment)		
	Mean age = 47.3 (SD 10.4)		
	Source = volunteers		
	Diagnosis = systemic lupus erythematosus		
	Mean years of pain = 11		
Interventions	"CBT with biofeedback"		
	"Symptom monitoring and support"		
	"Treatment as usual"		
Outcomes	Primary pain outcome: AIMS2 pain 0 to 10		
	Primary disability outcome: SF36 physical function (reversed)		
	Primary distress outcome: CES-D Depression		
	Arthritis Impact Measurement Scale (AIMS) 2: pain		
	Multidimensional Pain Inventory: interference		
	Center for Epidemiologic Studies Depression Scale (CES-D)		
	Arthritis Self-Efficacy		
	Perceived stress		
	Short Form 36 Physical functioning		
	Fatigue severity		
	Global self assessment		
	Disease activity systemic lupus activity measure-revised (SLAM-R)		
	Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)		
Notes	Funding statement: "Supported by a Robert Wood Johnson Clinical Science Grant from the Arthritis Foundation; a grant-in-aid from the American Heart Association; the Lupus Foundation of America, Western Pennsylvania Chapter; NIH grant 5-R01-HL-5490002; NIH/NCRR/GCRC grant 5-M01-RR-00056; NIH grant R01-AR-4658802; NIH gran K24-AR-02213; and NIH grant 2-R01-HL-5490005"		
	Conflict of interest statement: None included in paper		
	CBT versus AC, post-treatment and follow-up: analyses 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	CBT versus TAU, post-treatment and follow-up: analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
Risk of bias			
Bias	Authors' judgement Support for judgement		
Random sequence genera- tion (selection bias)	Low risk "assigned randomly, based on a software-generated randomization plan"		

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### Greco 2004 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Rheumatologist and researcher assessors masked to treatment assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Multiple imputation used for missing data; attrition > 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	Treatment credibility assessed and no significant differences between groups identified

# Haldorsen 1998

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, 1 year		
Participants	End of treatment n = 387		
	Start of treatment n = 469		
	Sex: 298 F, 171 M		
	Mean age = 43 (SD 10.6)		
	Source = National Insurance system contact		
	Diagnosis = mixed chronic pain		
	Mean years of pain = not given		
Interventions	"Cognitive behaviour therapy"		
	"Treatment as usual"		
Outcomes	Primary pain outcome: VAS pain		
	Primary disability outcome: none		
	<b>Primary distress outcome: HSCL distress</b> Visual analogue scale pain (in afternoon)		
	Physical training		
	Hopkins Checklist (HSCL) Distress (Norwegian version)		
	Attribution style		
	Work satisfaction		
	Ergonomic performance		
	Subjective health rating		



# Haldorsen 1998 (Continued)

Notes

Funding statement: None included in paper

Conflict of interest statement: None included in paper

CBT vs TAU follow-up: analyses 2.4, 2.6

# **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Allocated at random by cards in sealed envelopes
Allocation concealment (selection bias)	Low risk	Allocation sequence by someone not involved in study
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessment by physiotherapists who tried to remain blind to treatment
Incomplete outcome data (attrition bias) All outcomes	High risk	No method for dealing with missing data described; attrition > 10%
Selective reporting (re- porting bias)	High risk	Trial not pre-registered; outcomes not fully reported
Treatment expectations	Unclear risk	Not assessed

### Helminen 2015

Study characteristics	5	
Methods	RCT; 2 arms; assessed pre-treatment, 3 months, 12 months	
Participants	End of treatment (3 months) n = 101	
	Start of treatment n = 111	
	Sex: 77 F, 34 M	
	Mean age = 63.5 (SD 7.2)	
Source = rheumatology clinic		
	Diagnosis = knee osteoarthritis	
	Mean years of pain = 7.8 (SD 6.6)	
Interventions	Group CBT for pain management and GP care	
	Usual care = GP care	
Outcomes	<b>Primary pain outcome:</b> Western Ontario and McMaster Universities (WOMAC) Osteoarthritis index pain subscale VAS	
	Primary disability outcome: WOMAC Physical function self-report	

Helminen 2015 (Continued)	Primary distress outcome: Beck Depression Inventory
	Western Ontario and McMaster Universities (WOMAC) Osteoarthritis index pain
	Secondary outcomes: Pain self-report numerical pain rating scale
	WOMAC Physical function self-report
	WOMAC Stiffness
	Health-related quality of life RAND SF-36. 15D
	Beck Depression Inventory
	Life Satisfaction Scale
	Sense of Coherence Scale
	Pain Self-Efficacy Questionnaire
	Tampa Scale of Kinesiophobia
	Pain Catastrophising Scale
	Beck Anxiety Inventory
	Global Assessment of Change
	Use of analgesics
	Health care use
	Sick leave days
Notes	CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6
	Trial registration: ISRCTN 64794760
	Funding statement: "An EVO and a VTR grant from Kuopio University Hospital."
	Conflict of interest: "The authors declare that there is no conflict of interest"

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Independent computer-generated randomization
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes sequentially numbered; those administering were blind to group assignment
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Outcome assessment blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; ITT analysis by mixed models
Selective reporting (re- porting bias)	Low risk	Registered as ISRCTN 64794760: all outcomes reported



# Helminen 2015 (Continued)

Treatment expectations

Unclear risk

Not assessed

leutink 2012		
Study characteristics		
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 3 months	
Participants	Post-treatment n = 54	
	Start of treatment n = 61	
	Sex: 22 F, 39 M	
	Mean age = 58.8 (SD 11.4)	
	Source = Rehabilitation clinics	
	Diagnosis = Neuropathic pain (spinal cord injury)	
	Mean years of pain = 5.4	
Interventions	CBT "Multidisciplinary cognitive behavioral treatment program"	
	WLC "Wait-list control"	
Outcomes	Primary pain outcome: Chronic Pain Grade questionnaire pain intensity	
	Primary disability outcome: Chronic Pain Grade questionnaire pain disability	
	Primary distress outcome: Hospital Anxiety and Depression Scale (anxiety subscale, depression not reported)	
	Chronic Pain Grade questionnaire	
	Pain numerical rating scale	
	Coping Strategy Questionnaire Hospital Anxiety and Depression Scale	
	UAL participation in activities scale	
	Life Satisfaction Questionnaire LiSat-9	
Notes	CBT vs TAU, post-treatment: 2.1, 2.2	
	Funding statement: "This project is supported by an unrestricted Grant from Pfizer, Reference No. 007-04."	
	Conflict of interest statement: "The authors declare that they have no competing interests"	
Risk of bias		
Bias	Authors' judgement Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk Method of randomisation not described	

## Heutink 2012 (Continued)

Allocation concealment (selection bias)	Unclear risk	Treatment allocation not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No description
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; ITT analysis conducted but method for dealing with missing data described
Selective reporting (re- porting bias)	High risk	Trial protocol not published and authors do not provide means of measures that are non-significant in manuscript
Treatment expectations	Unclear risk	Not assessed

## Jensen 2001

Study characteristics			
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment, 6 months, 18 months, 3 years		
Participants	End of treatment n = 186		
	Start of treatment n = 214		
	Sex: 117 F, 93 M		
	Mean age = 43.3 (SD 10.4)		
	Source = pain or rehabilitation clinic		
	Diagnosis = mixed (mostly chronic low back pain)		
	Mean years of pain = 2.7		
Interventions	"CBT"		
	"Behavioural medicine rehabilitation"		
	"Behaviourally orientated physical therapy" (BT)		
	"Treatment as usual"		
Outcomes	Primary pain outcome: Short Form 36: pain (reversed)		
	Primary disability outcome: SF-36: physical functioning (reversed)		
	<b>Primary distress outcome: SF-36: mental health (reversed)</b> SF-36: Pain		
	SF-36: Physical Functioning		
	SF-36: Mental Health		
Notes	Funding statement: "This study was supported by AMF-sjukförsäkring, Stockholm, Sweden."		
	Conflict of interest statement: None included in paper		
	CBT vs TAU, post-treatment and follow-up (6 months): analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		



Jensen 2001 (Continued)

BT vs TAU, post-treatment and follow-up (6 months): analyses 4.1, 4.2, 4.3, 4.4, 4.5, 4.6

Baseline n used as n unavailable for post-treatment and follow-up results

## **Risk of bias**

Authors' judgement	Support for judgement
Low risk	Shuffled sealed envelopes
Low risk	Sealed envelopes; procedure by researchers blind to participant screening
Unclear risk	Data gathered by research team, unclear if blinded
High risk	ITT analyses conducted, no description of how missing data were handled; > 10% attrition
Unclear risk	Trial protocol not published
Unclear risk	Not assessed
	Low risk Low risk Unclear risk High risk Unclear risk

## Kaapa 2006

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months, 1 year, 2 years		
Participants	End of treatment n = 120		
	Start of treatment n = 132		
	Sex: 120 F, 12 M (start of treatment)		
	Mean age = 46.3 (SD 7.5)		
	Source = community		
	Diagnosis = chronic low back pain		
	Mean years of pain = 1.3		
Interventions	"semi-intensive multidisciplinary rehabilitation"		
	"individual physiotherapy"		
Outcomes	Primary pain outcome: pain intensity 0 to 10		
	Primary disability outcome: Oswestry Disability Index 0 to 100		
	Primary distress outcome: (DEPS) depression 0 to 30		
	Low back pain intensity 0 to 10		



Kaapa 2006 (Continued)			
	Sciatic pain intensity 0 to 10		
	Oswestry Disability Index 0 to 100		
	Subjective work capacity 0 to 10		
	Recent sick leave due to back pain		
	Beliefs re working (2-year follow-up) 0 to 10		
	The Depression Scale (DEPS) 0 to 30		
	Health care consumption 12 months		
Notes	Funding statement: "Foundation funds were received in support of this work."		
	Conflict of interest statement: None included in this paper CBT vs AC, post-treatment and follow-up: analyses 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"The randomization list was generated by an independent biostatistician us- ing a table of random numbers"
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes; numbers generated by independent statistician
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data methods not described, but "missing values in questionnaires were not substituted for"; Attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Low risk	Treatment expectations assessed: no significant differences identified be- tween the two groups

## Karlsson 2015

Study characteristics		
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6-, 12-months	
Participants	Post-treatment n = 47	
	Start of treatment n = 48	
	Sex: 48 F, 0 M	
	Mean age = 48.6 (SD 9)	

Karlsson 2015 (Continued)	Source = advertising in the local daily newspaper and an information meeting with the local branch of the Fibromyalgia Patient Association.		
	Diagnosis = fibromyalgia		
	Mean years of pain = 11.4 (SD 6.8)		
Interventions	CBT "Stress management cognitive behaviour therapy", group WLC "Wait list control"		
Outcomes	Primary pain outcome: West Haven-Yale Multidimensional Pain Inventory pain intensity		
	Primary disability outcome: West Haven-Yale Multidimensional Pain Inventory interference		
	Primary distress outcome: Montgomery-Åsberg Depression Rating Scale		
	Experienced important life events		
	West Haven-Yale Multidimensional Pain Inventory		
	Maastricht Questionnaire - fatigue		
	Everyday Life Stress		
	Montgomery-Åsberg Depression Rating Scale		
Notes	CBT vs TAU, post-treatment: 2.1, 2.2, 2.3		
	Funding statement: "This study was supported by grants from the Söderström-König Foundation (2003-139), the Swedish Rheumatism Association (51/04), the Swedish Social Insurance Agency (11124), Uppsala County Council (K2003-0036) and Uppsala University (UFV2003/39)."		
	Conflict of interest statement: "All authors declared that they have no conflicts of interest."		

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"The remaining 48 women agreed to participate and were using a random block design allocated into two groups, group 1 (n = 24) and group 2 (n = 24). The randomizaton was performed with the SAS function 'ranuni' that pro- duces random numbers with equal distribution, i.e., all numbers appear with the same probability. According to this design, for every four consecutive pa- tients, two were randomly allocated to group 1 and the remaining two were al- located to group 2."
Allocation concealment (selection bias)	Low risk	"The allocations were indicated on paper sheets and put in sealed envelopes with a patient serial number on the outside. The sheet furthermore had a dis- turbing text on the backside to prevent reading the allocation through the envelope. The envelopes were stored with the study monitor. When patients were included in the study, they were given a serial number, the correspond- ing serial number envelope was opened and the patient allocation was noted in the study chart."
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Partial non-response (missing data in returned questionnaires) was on aver- age 0.6% with a maximum in individual variables of 1.1%." Attrition < 10%; ITT analysis.



Karlsson 2015 (Continued)

Selective reporting (re- porting bias)	Unclear risk	In protocol (NCT01004458), secondary assessments include 'type A behaviour measures', not reported in the trial paper.
Treatment expectations	Unclear risk	Not assessed

## Keefe 1990

Study characteristics			
Methods	RCT. 3 arms; assessed pre-treatment, post-treatment, 6 months		
Participants	End of treatment n = 94		
	Start of treatment n = 99		
	Sex: 71 F, 28 M		
	Mean age = 64.0 (SD 11.5)		
	Source = rheumatology clinic		
	Diagnosis = osteoarthritis of the knee		
	Mean years of pain = 12.0		
Interventions	"coping skills training"		
	"arthritis education"		
	"standard care"		
Outcomes	Primary pain outcome: AIMS pain		
	Primary disability outcome: AIMS physical disability		
	<b>Primary distress outcome: AIMS psychological disability</b> Arthritis Impact Measurement Scale (AIMS): pain		
	AIMS: psychological disability		
	AIMS: physical disability		
	Pain behaviour (Keefe & Block) observation		
	Coping Strategy Questionnaire		
	Medication use		
Notes	Funding statement: "Supported by NIAMS grant AR-35270"		
	Conflict of interest statement: None included in this paper		
	CBT vs AC, post-treatment and follow-up: analyses 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	CBT vs TAU, post-treatment and follow-up: analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
Risk of bias			
Bias	Authors' judgement Support for judgement		



## Keefe 1990 (Continued)

Random sequence genera- tion (selection bias)	Low risk	"randomly assigned (using a random number table)"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data methods not described; attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Low risk	Treatment credibility assessed: no significant differences between the two groups identified

## Keefe 1996

Study characteristics	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months, 1 year
Participants	End of treatment n = 82
	Start of treatment n = 88
	Sex: 54 F, 34 M
	Mean age = 62.6 (SD 10.1)
	Source = volunteer
	Diagnosis = osteoarthritis of knee
	Mean years of pain = 10.7
Interventions	"spouse-assisted coping skills training"
	"coping skills training"
	"spouse-supported arthritis education"
Outcomes	Primary pain outcome: AIMS pain
	Primary disability outcome: AIMS physical disability
	Primary distress outcome: AIMS mental disability Arthritis Impact Measurement Scale (AIMS): pain
	AIMS: physical
	AIMS: psychological
	Coping Strategies Questionnaire (CSQ): coping

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Keefe 1996 (Continued)	
	CSQ: pain control
	Pain behaviour (Keefe & Block) observation
Notes	Funding statement: "Supported by NIAMS grant AR-35270"
	Conflict of interest statement: None included in this paper
	CBT vs AC, post-treatment: analyses 1.1, 1.2, 1.3
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned": method not described
Allocation concealment (selection bias)	Unclear risk	Not reported (but equal credibility of treatments rated by participants)
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data methods not described; attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Unclear risk	Treatment credibility assessed, and significant differences found on how log- ical treatment was perceived as. Participants in the spouse-supported group rated the treatment more logical than participants in the conventional group.

## Kole-Snijders 1999

Study characteristics	s	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months, 1 year	
Participants	End of treatment n = 133	
	Start of treatment n = 148	
	Sex: 94 F, 54 M	
	Mean age = 30.8 (SD 9.1)	
	Source = pain or rehabilitation clinic	
	Diagnosis = chronic low back pain	
	Mean years of pain = 9.8	
Interventions	"operant + cognitive coping skills"	
	"operant + group discussion"	



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## Kole-Snijders 1999 (Continued)

<b>ole-Snijders 1999</b> (Continued)	"waiting list"		
Outcomes	Primary pain outcome: no data available Primary disability outcome: no data available		
	Primary distress outcome: no data available		
	(all reduced by factor a	nalysis to 3 scores: motoric, coping control, negative affect)	
	Pain Behaviour Scale		
	Checklist for Interpersonal Pain Behaviour		
	Behavioural approach	test (walking distance)	
	Multi-dimensional Loci	us of Control	
	Pain Cognition Checklis	st	
	Coping Strategies Questionnaire		
	Nijmegen Hyperventilation Questionnaire		
	Visual analogue scale:	pain	
	McGill Pain Questionnaire: pain		
Notes	Funding statement: "This research was spported by Grant OG 91-088 from the Investigative Medicine Fund of the Dutch Insurance Council"		
	Conflict of interest statement: None included in this paper		
	No data provided		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	"independent researcher blindly drew [numbers assigned randomly to pa- tients] and assigned to one of three conditions"	
Allocation concealment (selection bias)	Low risk	Independent researcher	
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessor unaware of treatment condition	
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT analyses completed with missing values of dropouts replaced by mean score of least favourable quartile of patients at the respective measurement; attrition = 10%	
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published	



tion (selection bias)

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## Kraaimaat 1995

Study characteristics			
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months		
Participants	End of treatment n = 52		
	Start of treatment n = 58		
	Sex: 52 F, 25 M (from the 77 who agreed to participate)		
	Mean age = 57.0 (SD 12.7)		
	Source = rheumatology clinics		
	Diagnosis = rheumatoid arthritis		
	Mean years of pain = 15.6		
Interventions	"cognitive behavioural therapy"		
	"occupational therapy"		
	"waiting list"		
Outcomes	Primary pain outcome: IRGL pain		
	Primary disability outcome: IRGL function (Reversed)		
	Primary distress outcome: IRGL depression		
	Invloed van Reuma op Gezondheid en Leefwijze (IRGL): function		
	IRGL: self care		
	IRGL: pain		
	IRGL: anxiety		
	IRGL: depression		
	IRGL: potential support		
	IRGL: actual support		
	IRGL: mutual visits		
Notes	Funding statement: "The study was funded by a grant from the Dutch League Against Rheumatism ('Na- tionaal Reumafonds')"		
	Conflict of interest statement: None included in this paper		
	CBT vs AC, post-treatment and follow-up: analyses 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	CBT vs TAU, post-treatment and follow-up: n < 20		
Risk of bias			
Bias	Authors' judgement Support for judgement		
Random sequence genera- tion (selection bias)	Unclear risk "randomly assigned" (method not described)		



## Kraaimaat 1995 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Fully reported; several differences between dropouts and completers. Completer analyses conducted; attrition = 10%
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Unclear risk	Not assessed

## Lera 2009

Study characteristics	
Methods	RCT; 2 arms; assessed pretreatment, post-treatment, 6 months
Participants	Post-treatment n = 66
	Start of treatment n = 83
	Sex: 83F, 0 M
	Mean age = 51.2 (SD 8.7)
	Source = Fibromyalgia clinic
	Diagnosis = Fibromyalgia
	Mean years of pain = 16.5 (10.6)
Interventions	MT + CBT: "Multidisciplinary treatment with CBT (Multidisciplinary treatment includes exercise, drugs, education)"
	MT: "Multidisciplinary treatment "
Outcomes	Primary pain outcome: None
	Primary disability outcome: Fibromyalgia Impact Questionnaire (physical functioning)
	Primary distress outcome: Symptoms Checklist-90 Revised
	Fibromyalgia Impact Questionnaire
	Medical Outcomes Short Form SF-36 Symptoms Checklist-90 Revised
Notes	CBT vs AC, post-treatment and follow-up: 1.2, 1.3, 1.5
	Funding statement: None included in paper
	Conflict of interest statement: None included in paper
Risk of bias	

**Risk of bias** 



## Lera 2009 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"randomly assigned (by the flip of a coin) to either the MT group or the MT +CBT group"
Allocation concealment (selection bias)	Unclear risk	No description
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	"A resident physician specifically trained and blinded to the group assignation explored the 18 bilateral pairs of tender points related to FM." No description of assessors being blinded for other outcomes
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 20%; no description of dealing with incomplete data
Selective reporting (re- porting bias)	Unclear risk	No trial registration
Treatment expectations	Unclear risk	Not assessed

## Lindell 2008

Study characteristics	5
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 18-month follow-up
Participants	End of treatment n = 123
	Start of treatment n = 125
	Sex: 68 F, 57 M
	Mean age = 42.6 (SD not given)
	Source = primary care
	Diagnosis = non-specific back or neck pain
	Mean years of pain = not given but had to be sick-listed for more than 6 weeks (up to 2 years); mean > 7 months sick-listed
Interventions	"Cognitive-behavioural rehabilitation"
	"Primary care"
Outcomes	Primary pain outcome: none
	Primary disability outcome: none
	Primary distress outcome: none
	Sick-listed days
	Health care visits
Notes	Funding statement: "This study was supported by grants from the Stockholm County Social Insurance Agency, Stockholm County Council, Ministry of Health and Social Affairs, Vårdal Foundation, Cardionics and Pharmacia (now part of Pfizer)."



Lindell 2008 (Continued)

Conflict of interest statement: "The authors declare that they have no competing interests."

No data provided

## **Risk of bias**

Authors' judgement	Support for judgement
Low risk	Computerised block randomisation procedure
Low risk	Randomisation generated by independent statistician; in opaque envelopes
High risk	Assessors not blind to treatment condition, except for sick-listing outcome
Low risk	ITT analyses and completer analyses conducted. No description of how miss- ing data were handled. Attrition < 10%
Unclear risk	Trial protocol not published
Unclear risk	Not assessed
	Low risk Low risk High risk Low risk Unclear risk

#### Litt 2009

Study characteristics	3	
Methods	RCT; 2 arms; CBT + standard treatment; standard treatment; assessed post-treatment	
Participants	End of treatment: n = 54	
	Start of treatment: n = 54	
	Sex: 46 F; 8 M	
	Mean age: 41.0 (SD 11.0)	
	Source = dental clinics and dentists (15%); newspaper and web adverts (85%)	
	Diagnosis = temporomandibular disorder	
	Mean years of pain: 5.6 (SD 5.4)	
Interventions	CBT + standard treatment; standard treatment (splint, diet, NSAIDs)	
Outcomes	Primary pain outcome: MPI pain severity 0 to 6	
	Primary disability outcome: MPI pain interference 0 to 6	
	Primary distress outcome: CES-D	
	Pain Intensity MPI 0 - 6	
	CES-D Depression	

Litt 2009 (Continued)	Interference with activity MPI 0 - 6
	2 items modified from Catastrophising Sub-Scale CSQ
	Several times daily sampling of pain, control, affect, coping, catastrophising
Notes	Funding statement: ""Support for this project was provided by Grants R01-DE14607 from the Nation- al Institute on Dental and Craniofacial Research, and by General Clinical Research Center Grant M01- RR06192 from the National Institutes of Health. "
	Conflict of interest statement: "None of the authors have any financial or other relationships that might lead to a conflict of interest."
	CBT vs TAU: analyses 2.1, 2.2, 2.3
	2011 update search

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Computerised urn randomisation"
Allocation concealment (selection bias)	Unclear risk	"The Project Coordinator entered the urn data during the intake session and informed the participants of their treatment assignments." Unclear if alloca- tion was concealed from participants
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Did not report flow of participants in the study or attrition throughout the study. Appears they have conducted completer analyses
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Unclear risk	Not assessed

## Luciano 2014

## Study characteristics

Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months	
Participants	End of treatment n = 142	
	Start of treatment n = 156	
	Sex: 150 F, 6 M	
	Mean age = 48.3 (SD 5.8)	
	Source = primary care	
	Diagnosis = fibromyalgia	
	Mean years of pain = not stated	
Interventions	"Group ACT"	
	"Pharmacological treatment"	



## Luciano 2014 (Continued)

Luciano 2014 (Continuea)	"Waiting list"
Outcomes	Primary pain outcome: Pain Visual Analogue Scale (0 to 100) Primary disability outcome: Fibromyalgia Impact Questionnaire Primary distress outcome: HADS-D Pain Catastrophizing Scale Hospital Anxiety & Depression Scale A & D Euro-Quality of Life (EQ5-D) VAS Chronic Pain Acceptance Questionnaire Adverse events
Notes	ACT vs TAU: analyses 6.1, 6.2, 6.3, 6.4, 6.5, 6.6 Funding statement: no funding declared Conflict of interest statement: "The authors report no conflict of interest."

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"with a random allocation of the participants into 3 conditions (using a com- puter-generated randomization list)"
Allocation concealment (selection bias)	Low risk	By research assistant not involved in the study
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Study personnel who conducted the interviews and assessed the outcomes were blinded to treatment allocation"
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis with multiple imputation of missing data; attrition < 10%
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not published
Treatment expectations	Unclear risk	Not assessed

## Lumley 2014

Study characteristics	S	
Methods	RCT; 4 arms; assessed pre-treatment; post-treatment (1 month), 4- and 12-month follow-up	
Participants	End of treatment: n = 245	
	Start of treatment: n = 264	
	Sex: 214 F; 50 M	
	Mean age: 55.1 (SD 12.1)	
	Source = rheumatology clinics and community	
	Diagnosis = rheumatoid arthritis	
	Mean years of pain: 13.2 (SD 11.3)	



Lumley 2014 (Continued)				
Interventions	CST+WED CST coping skills training (CBT) and emotional disclosure writing			
	CST+CW coping skills training (CBT) and control writing (time management)			
	CT+WED control training (arthritis education) and emotional disclosure writing			
	CT+CW control training and control writing			
	Control training was matched for time etc. with CST, and control writing with WED.			
Outcomes	Primary pain outcome: AIMS pain scale			
	Primary disability outcome: AIMS disability scale			
	Primary distress outcome: AIMS anxiety & mood scales combined			
	Arthritis Impact Measure Scales-2 (AIMS-2)			
	Disease activity (primary outcome of writing intervention): swelling & tenderness in 16 joints, assessed by blind rheumatologist			
	MPQ sensory and affective pain scores			
	Walking speed over 50ft, assessed blind to allocation			
	Inflammatory activity (C-reactive protein)			
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6			
	Trial registration: clinical trials.gov NCT00088764			
	Funding statement: "This research was funded by National Institute of Arthritis and Musculoskeletal and Skin Diseases Award AR049059, part of the National Institutes of Health (NIH), and by National In- stitute of Arthritis and Musculoskeletal and Skin Diseases Awards AR057808 and AR057047."			
	Conflict of interest statement: None included in this paper			

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Prior to recruitment, a person independent of the study staff used randomiza- tion software to develop the condition assignments. To balance the conditions by important variables, randomization was stratified by the two study sites as well as three current medication classes." "Randomization was done in blocks of eight patients to one of two writing conditions (WED or control writing) and one of two training conditions (CST or education control), and assignments were sealed in envelopes."
Allocation concealment (selection bias)	Low risk	"At the end of the pretreatment evaluation, the research assistant and each patient jointly opened the next envelope in the sequence, which contained the patient's randomly assigned writing and training conditions."
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessments by staff who were blind to allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; mixed models used, and ITT analyses.



Unclear risk

## Lumley 2014 (Continued)

Selective reporting (re-	Unclear risk
porting bias)	

 ${\it Slight\ changes\ in\ outcomes\ compared\ with\ trial\ registration\ document}$ 

Treatment expectations

Not assessed

## Lumley 2017

Study characteristics	
Methods	Cluster RCT; 3 arms; assessed pre-treatment, post-treatment, and 6 months
Participants	Post-treatment n = 216
	Start of treatment n = 230
	Sex: 216 F, 14 M
	Mean age = 49.1 (SD 12.2)
	Source = communities
	Diagnosis = fibromyalgia
	Mean years of pain = 13.6 (SD 10.5)
Interventions	EAET "Emotional awareness and expression therapy"
	CBT "Thoughts and behaviors treatment"
	Education "Fibromyalgia education"
Outcomes	Primary pain outcome: Brief Pain Inventory pain severity
	Primary disability outcome: 12-item Short-form Health Survey physical component scores
	Primary distress outcome: Center for Epidemiological Studies-Depression Scale
	Brief Pain Inventory
	Pittsburgh Sleep Quality Index
	Multiple Ability Self-Report Questionnaire for cognitive dysfunction
	Center for Epidemiological Studies-Depression Scale
	Generalised Anxiety Disorder-7
	PROMIS Fatigue short form
	SF-12 Health Survey physical component score
	Positive Affect Negative Affect Schedule
	Satisfaction with Life Scale
	Number of time the patient had seen a physician or other health care professional for treatment of ill- ness or symptoms during the last three months
	Patient Global Impression of Change
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6



Lumley 2017 (Continued)

#### Trial registration: NCT01287481

Funding statement: "This research was funded by the National Institute of Arthritis, Musculoskeletal, and Skin Diseases, part of the National Institutes of Health, under award number AR057808. The content, including study design, data collection, data analysis, interpretation of data, writing of the report, and the decision to submit the report, is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Conflict of interest statement: "S. E. Harte has received personal fees from Cerephex, Forest Laboratories, Eli Lilly, Merck, and Aptinyx; serves or has served as a consultant for Pfizer, Regeneron, Analgesic Solutions, Aptinyx, Longitude Capital Management, and deCode Genetics; is a member of Arbor Medical Innovations, LLC; and has received non-financial support from Coy Labs. D. J. Clauw has received personal fees from Abbott Pharmaceutical, Aptinyx, Astellas Pharmaceutical, Cerephex, Daiichi Sankyo, Pfizer, Samumed, Theravance, Tonix, Williams & Connolly LLP, and Zynerba and has received research support from Aptinyx, Cerephex, and Pfizer. D. A. Williams serves as a consultant to Community Health Focus Inc and is an honorarium recipient from Pfizer as grant reviewer through the American Pain Society. He is the President of the American Pain Society. The remaining authors have no conflict of interest to declare."

#### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"An independent statistician generated computer randomization sequences, separately for each site, in randomized blocks of 6 clusters (with the final clus- ter in each block re-randomized to prevent staff unblinding)"
Allocation concealment (selection bias)	Low risk	"assignments were placed in sealed, opaque envelopes"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Each patient then had a pretreatment assessment by a blinded research assistantPatients had 3 assessments conducted by blinded research as- sistants: at pretreatment (2 weeks before randomization), posttreatment (2 weeks after session 8), and follow-up (6 months after session 8). Patient-re- ported outcomes were administered via computer in a supervised setting"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Multiple imputation for missing data; < 10% attrition
Selective reporting (re- porting bias)	High risk	Trial pre-registered (NCT01287481). Secondary outcomes listed in the protocol not reported in manuscript
Treatment expectations	Low risk	Treatment expectancy assessed: no significant differences found

#### Macrae 2019

Study characteristics	
Methods	RCT; 3 arms; assessment pre-treatment, post-treatment, 6 month follow-up
ParticipantsEnd of treatment n = 85	
	Start of treatment n = 113
	Sex: 110 F, 3 M
	Mean age = 52.7 (SD 11.0)



Acrae 2019 (Continued)		
	Source = rheumatology and sleep clinics	
	Diagnosis = fibromyalgia and insomnia	
	Mean years of pain = 8.9 (s.d. 7.3)	
Interventions	CBT for insomnia: CBT-I	
	CBT for pain: CBT-P	
	- these two arms were combined for analysis	
	Control: waiting list	
Outcomes	Primary pain outcome: McGill Pain Questionnaire (MPQ) total pain 0-78	
	Primary disability outcome: Pain Disability Inventory (PDI)	
	Primary distress outcome: Beck Depression Inventory version II (BDI-II)	
	State-Trait Anxiety Inventory (STAI)	
	Morning and evening pain intensity (VAS)	
	Self-reported diary including sleep onset latency, sleep efficiency	
	Dysfunctional beliefs and attitudes about sleep questionnaire	
	Actigraphy	
	Ambulatory polysomnography	
Notes	CBT vs TAU post-treatment and 6 month follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6	
	Funding statement: grant from the National Institute of Arthritis and Musculoskeletal and Skin Disease R01AR055160	
	Conflict of interest: none declared.	
Risk of bias		
Bias	Authors' judgement Support for judgement	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"randomly assigned to condition by computer-generated block randomisa- tion"; block size 6
Allocation concealment (selection bias)	Unclear risk	"team members involved in recruitment, data collection, and statisticians who conducted the analysis, were masked to assignment" - not clear if this applies to allocation
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"collected by a researcher not involved in treatment"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No description of how data imputed; ITT analysis
Selective reporting (re- porting bias)	High risk	Different primary and secondary outcomes between protocol and trial; addi- tional outcomes in trial compared to protocol
Treatment expectations	Unclear risk	Not assessed



## Mangels 2009

Study characteristics			
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 12 months		
Participants	Post-treatment n = 340		
	Start of treatment n = 363		
	Sex: 282 F, 81 M		
	Mean age = 48.8 (SD 13.1)		
	Source = orthopaedic rehabilitation department		
	Diagnosis = chronic lov	v back pain	
	Mean years of pain = no	ot stated	
Interventions	BMR "Behavioral-medi	cal rehabilitation" equivalent to CBT	
	BMR-B "Behavioral-me	dical rehabilitation with booster"	
	TOR "Traditional orthopedic rehabilitation": medical care, physiotherapy, occupational therapy		
Outcomes	Primary pain outcome: Pain Perception Scale		
	Primary disability outcome: Pain Disability Index		
	Primary distress outcome: Beck Depression Inventory		
	Pain Disability Index		
	Beck Depression Inventory		
	Pain Perception Scale, 24 items rated 1-4, 4 is worst		
	SF-36		
	German Pain Managen	nent Questionnaire	
	Pain Self-Efficacy Questionnaire		
	German Life Satisfaction Questionnaire		
Notes	CBT vs AC post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	Funding statement: "Supported in part by the Deutsche Rentenversicherung Bund (the German Annu- ity Insurance Association)."		
	Conflict of interest statement: None included in paper		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Randomization was carried out by an administration secretary of the rehabili- tation hospital who received random numbers from the study center, and who was not involved in further treatment decisions"	



## Mangels 2009 (Continued)

Allocation concealment (selection bias)	Low risk	"Randomization was carried out by an administration secretary of the rehabili- tation hospital who received random numbers from the study center, and who was not involved in further treatment decisions"
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No description
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Missing values owing to dropout were imputed using the last known value carried forward, thus all of the patients were further analyzed as intended to treat." Attrition < 10%.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

## Martin 2012

Study characteristics	5
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6-months
Participants	Post-treatment n = 126 but results only for 110 at 6 month follow-up
	Start of treatment n = 153
	Sex: 100 F, 10 M
	Mean age = 50.2 (SD 9.3)
	Source = pain management clinic
	Diagnosis = fibromyalgia
	Mean years of pain = 14.1 (10.0)
Interventions	Experimental group EG / PSYMEPHY "Psychological, medical, educational, and physiotherapeutic com- ponents"
	Control group CG "Standard pharmacological care"
Outcomes	Primary pain outcome: Fibromyalgia Impact Questionnaire (FIQ) pain intensity
	Primary disability outcome: Fibromyalgia Impact Questionnaire (FIQ) total score
	Primary distress scale: Hospital Anxiety and Depression Scale (HADS) depression subscale
	Coping with Chronic Pain Questionnaire (CAD-R)
	Functional sexual support questionnaire (Duke-UNC)
	Satisfaction with treatment
Notes	Data only at 6 months
	Funding statement: "this study was carried out with funding from Department of Health of the Basque Country (project nº 2006111057), "Improvement of the health-related quality of life of patients suffering

#### Martin 2012 (Continued)

from fibromyalgia using multidisciplinary treatment" granted to Fernando Torre, the principal investigator."

Conflict of interest statement: "none declared"

NCT01266733

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"a list of random numbers was developed by the statistician, so that patients could be randomly assigned to the experimental (EG) or control group (CG). Randomisation was made by means of an electronic numbers generator (SPSS)."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The self-administered questionnaires were collected by a researcher who was not involved in providing treatment"
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10% and dealing with missing data not described
Selective reporting (re- porting bias)	High risk	Trial was pre-registered but extra outcomes in trial not in protocol
Treatment expectations	Unclear risk	Not assessed

## McCracken 2013

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, and 3 months
Participants	Post-treatment n = 58 Start of treatment n = 73
	Sex: 50 F, 23 M
	Mean age = 58 (SD 12.8)
	Source = GP referrals
	Diagnosis = mixed chronic pain conditions
	Median years of pain = 10 years
Interventions	ACT "Acceptance & Commitment Therapy"
	TAU "Treatment as usual"
Outcomes	Primary pain outcome: pain numerical rating scale
	Primary disability outcome: Roland & Morris disability questionnaire



McCracken 2013 (Continued)	
	Primary distress outcome: PHQ-9 depression
	Roland and Morris Disability Questionnaire
	Short Form Health Survey (SF-36)
	0 to 10 numerical rating of average pain intensity
	Patient Health Questionnaire 9 - depression
	Patient Global Impression of Change
	Medication changes
	Treatment processes
	Chronic Pain Acceptance Questionnaire
	Acceptance Action Questionnaire-II
Notes	ACT vs TAU: analyses 6.1, 6.2, 6.3
	Trial registration: ISRCTN49827391
	Funding statement: "This research was funded by the UK National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme."

Conflict of interest statement: "The authors report no conflict of interests."

Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Participants were randomized to ACT plus treatment-as-usual (TAU) or TAU alone (1:1) based on computer-generated random numbers"
Allocation concealment (selection bias)	High risk	"allocation was not concealed"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"assessment and data entry were conducted blind to allocation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Next, an intention-to-treat (ITT) approach to these same analyses was used with imputation of missing data by last value carried forward." Attrition > 10%
Selective reporting (re- porting bias)	High risk	Primary outcomes in trial registration different to those in paper (Trial regis- tration ISRCTN49827391)
Treatment expectations	Unclear risk	Not assessed

## Mishra 2000

Study characteristics	
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment
Participants	End of treatment n = 94



lishra 2000 (Continued)			
	Start of treatment n = 94		
	Sex: 77 F, 7 M		
	Mean age = 35.8 (SD 9.9)		
	Source = pain or rehabilitation clinic and volunteer		
	Diagnosis = temporomandibular joint disorder		
	Mean years of pain = 7.0		
Interventions	"Biofeedback" (BT)		
	"Cognitive behavioural skills training" (CBT)		
	"Cognitive behavioural skills training + biofeedback"		
	"no treatment control"		
Outcomes	Primary pain outcome: CPI pain index		
	Primary disability outcome: none available		
	Primary distress outcome: none available		
	Characteristic Pain Index (CPI) pain severity 0 to 100		
	Graded Chronic Pain Score		
	Profile of Mood States total		
Notes	Funding statement: "This research was supported by GrantsROIDE10713 and K02MH01107 awarded to Dr. Gatchel from the National Institutes of Health."		
	Conflict of interest statement: None included in paper		
	Conflict of interest statement: None included in paper CBT versus TAU, post-treatment: analysis 2.1		

	Authonal independent	Current few indeement
Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"patients were assigned to group in a semi-random fashion using the urn method of random assignment"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition not reported; completer analysis
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered



## Mishra 2000 (Continued)

Treatment expectations

Unclear risk

Not assessed

Aiziara 2009		
Study characteristics		
Methods	RCT; 2 arms; assessed pre-treatment and post-treatment	
Participants	Post-treatment n = 44	
	Start of treatment n = 44	
	Sex: 29 F, 15 M	
	Mean age = 55 (SD 6.7)	
	Source = stomatology outpatient, hospital	
	Diagnosis = burning mouth syndrome	
	Mean years of pain = not stated	
Interventions	"Group psychotherapy" "Placebo pills"	
Outcomes	Primary pain outcome: short form McGill Pain Questionnaire	
	Primary disability outcome: none	
	Primary distress outcome: none	
	McGill Pain Questionnaire	
Notes	Not analysed: "other"	
	Funding statement: None included in paper	
	Conflict of interest statement: None included in paper	
Risk of bias		
Bias	Authors' judgement Support for judgement	
Random sequence genera-	Unclear risk Participants randomised but no method described	

tion (selection bias)		
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not described - assessment self-report only
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition reported



## Miziara 2009 (Continued)

Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

## Monticone 2013

Study characteristics			
Methods	RCT; 2 arms; assessed p	pre-treatment, post-treatment and 12 months	
Participants	Post-treatment n = 90		
	Start of treatment n = 90		
	Sex: 52 F, 38 M		
	Mean age = 49.3 (SD 7.5)		
	Source = hospital		
	Diagnosis = chronic low	v back pain	
	Mean years of pain = 2.	1 (SD 1.0)	
Interventions	CBT "Cognitive behavio	oural therapy" plus exercise	
	Exercise alone "Exercis	e training"	
Outcomes	Primary pain outcome: Numerical rating scale		
	Primary disability outcome: Roland-Morris Disability Questionnaire		
	Primary distress outcome: Short Form-36 Health Survey (mental health subscale)		
	Roland-Morris Disability Questionnaire		
	Tampa Scale for Kinesiophobia		
	Numerical rating scale pain Short-Form (36) Health Survey		
	Global perceived effect of treatment		
Notes	CBT vs AC, post-treatment and follow-up: 1.2, 1.3, 1.4, 1.5, 1.6		
	Funding statement: None included in paper		
	Conflict of interest statement: "The authors declare no conflict of interest."		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	Randomised using (SAS PROC PLAN)16	
Allocation concealment (selection bias)	Low risk	"Immediately after the patients had given their consent, the physiatrists e- mailed the Principal Investigator, who randomized the patients to one of the 2 treatment programs using a list previously generated by a biostatistician (SAS	



## Monticone 2013 (Continued)

		PROC PLAN)16 and delivered to the Principal Investigator with blinded treat- ment codes."
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The Principal Investigator obtaining and assessing the outcome data, and the biostatisticians making the analyses, were all blinded to the treatments"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition during study. Method to deal with missing data not described as not needed
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed but patients informed that neither treatment had established ef- ficacy

Monticone 2016	
Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 12-, 24 months
Participants	Post-treatment n = 147
	Start of treatment n = 150
	Sex: 92 F, 58 M
	Mean age = 53.5 (SD 10.8)
	Source = outpatient clinic (unclear on department)
	Diagnosis = chronic low back pain
	Mean years of pain = 1.9 (SD 1.3)
Interventions	Experimental group EG "Cognitive behavioural therapy (group-based)" with exercise
	Control group CG "Usual care" exercises
Outcomes	Primary pain outcome: Numerical Rating Scale
	Primary disability outcome: Oswestry Disability Questionnaire
	Primary distress outcome: PCS
	Oswestry Disability Questionnaire
	Tampa Scale for Kinesiophobia
	Pain Catastrophizing Scale
	Numerical Rating Scale
	Short Form Health Survey SF36 quality of life
	Global perceived effect GPE
	Adverse effects or distressing symptoms



## Monticone 2016 (Continued)

Notes

CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.4, 1.5

Funding statement: "None"

Conflict of interest statement: "None declared."

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Immediately after the patients had given their consent, the physiatrists mailed the principal investigator, who randomized the subjects to one of the two treatment programmes using a list of blinded treatment codes previous- ly generated by a biostatistician using an automatic assignment system to as- sure the concealment of the allocation."
Allocation concealment (selection bias)	Low risk	"automatic assignment to assure the concealment of the allocation"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The principal investigator obtaining and assessing the data and the biostatis- tician making the analyses, were both blinded to the treatment allocation"
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Since an intention-to-treat analysis was conducted, the linear mixed model was selected to better deal with missing data." No description of how missing data were dealt with. Attrition < 10%.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

## Monticone 2017

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 12-months		
Participants	Post-treatment n = 163		
	Start of treatment n = 170		
	Sex: 121 F, 49 M		
	Mean age = 52.9 (SD 12.7)		
	Source = hospital outpatients		
	Diagnosis = neck pain		
	Mean years of pain = 2.0 (SD 1.7)		
Interventions	Experimental group EG "Multidisciplinary treatment" CBT plus exercises		
	Control group CG "General exercise group" physiotherapy		
Outcomes	Primary pain outcome: Numerical rating scale		



Monticone 2017 (Continued)	Primary disability outcome: Neck Disability Index		
	Primary distress outcome: None		
	Neck Disability Index 0-100 where 100 is total disability		
	Tampa Scale for Kinesiophobia		
	Pain Catastrophizing Scale		
	Numerical rating scale for pain		
	Short-Form Health Survey SF36		
	Global Perceived Effect Scale		
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.4, 1.5		
	Trial registration: ISRCTN14581536		
	Funding statement: "The author(s) received no financial support for the research, authorship, and/or publication of this article."		
	Conflict of interest statement: "The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article."		

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Once the patient gave their consent, the biostatistician randomized the sub- ject to one of the two treatment programmes using a permuted-block ran- domization procedure. "
Allocation concealment (selection bias)	Low risk	"The list of treatment codes was previously generated and stored in Matlab and an automatic assignment system, also developed in Matlab, was used to conceal the allocation."
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The principal investigator obtaining and assessing the data and the biostatis- tician making the analyses were blinded to treatment allocation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Intention-to-treat analysis was conducted and linear mixed model analyses for repeated measures were made for each of the outcome measures to evalu- ate changes over time and between groups." Attrition < 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (ISRCTN14581536) and outcomes in protocol match those in paper
Treatment expectations	Unclear risk	Not assessed

## Nicassio 1997

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months
Participants	End of treatment n = 71

Nicassio 1997 (Continued)			
	Start of treatment n = 9	6	
	Sex: 63 F, 8 M (at follow	-up)	
	Mean age = 53.1 (SD not given)		
	Source = pain or rehabilitation clinic, support groups		
	Diagnosis = fibromyalg	ia	
	Mean years of pain = 11	.1	
Interventions	"behavioural treatmen	t"	
	"education"		
Outcomes	Primary pain outcome	e: not available	
	Primary disability out	come: quality of well being	
	Primary distress outco	ome: CES-D Depression	
	Pain index: composite eas, and flare index	of Fibromyalgia Impact Questionnaire pain scale, MPQ PRI, number of body ar-	
	Pain Behavior Checklis	t self-reported pain behaviour	
	Pain behaviour (Keefe &	& Block) observation	
	Center for Epidemiologic Studies Depression Scale (CES-D)		
	Rheumatology Attitudes Index helplessness subscale		
	Pain Management Inventory active and passive coping		
	Quality of Wellbeing Scale QWB: structured interview on functional impairment		
	Quality of Social Support Scale		
	Myalgia score, nurse rated on examination		
Notes	Funding statement: "Partially supported by Multipurpose Arthritis and Musculoskeletal Diseases Cen- ter Grant AR40770 to the University of California, San Diego, and a grant from the General Clinical Re- search Centers M01RR00827 of the MCRR from UA National Institutes of Health"		
	Conflict of interest statement: None included in paper		
	BT vs AC, post-treatment and follow-up: analyses 3.2, 3.3, 3.5, 3.6		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	In blocks, "randomly assigned, using a random numbers table"	
Allocation concealment (selection bias)	Unclear risk	Not reported	
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported	

## Nicassio 1997 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; no description of how missing data were dealt with
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	Treatment credibility assessed: no significant differences between groups

## Nicholas 2013

Study characteristics	
Methods	RCT; 3 arms; assessed pretreatment, post-treatment, 1-month
Participants	Post-treatment n = 130
	Start of treatment n = 141
	Sex: 89 F, 52 M
	Mean age (minimum 65y) = 73.9 (SD 6.5)
	Source = chronic pain clinics
	Diagnosis = Mixed chronic pain conditions
	Mean years of pain = not stated
Interventions	CBT "Pain self-management group", CBT and exercise
	EAT "Exercise-attention control" WLC "Waiting-list control"
Outcomes	Primary pain outcome: Numerical rating scale (usual pain)
	Primary disability outcome: Roland & Morris Disability Questionnaire-Modified
	Primary distress outcome: Depression scale of the Depression Anxiety Stress Scales
	Roland & Morris Disability Questionnaire-Modified
	Depression scale of the Depression Anxiety Stress Scales DASS-21
	Numerical rating scale (usual pain)
	Numerical rating scale (pain-related distress)
	Distance walked in 6 min (at a comfortable pace around a corridor course)
	Functional reach test
	Treatment mediators
	Pain Response Self-statements Scale catastrophising subscale
	Tampa Scale for Kinesiophobia
	Pain Self-Efficacy Questionnaire
Notes	CBT vs AC, post-treatment: 1.1, 1.2, 1.3

Nicholas 2013 (Continued)

CBT vs TAU, post-treatment: 2.1, 2.2, 2.3

Trial registration: ACTRN012606000124538

Funding statement: "This study was supported by a Grant from the Australian Health Ministers' Advisory Council (Grant: AHMAC PDR 2005/08)."

Conflict of interest statement: "There is no financial or other relationship that might lead to a conflict of interest."

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Another researcher (separate from the assessment and treatment teams) used block randomization methods [1] to randomly allocate groups to one of 3 conditionsPublished random number tables were also used"
Allocation concealment (selection bias)	Low risk	"allocated to groups of 5–10 patients by a researcher not involved in recruit- ment or treatmentThe order and identity of the treatment condition for each group was securely held by the randomizing researcher alone and only made known to the treatment team a few days before the treatment started"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The pretreatment, posttreatment, and 1-month follow-up assessments were conducted by an external research assistant who was blinded to the na- ture of the treatment being received by the participants. The same person also conducted additional performance measures according to standardised crite- ria"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	LOFC analysis used; attrition < 10% for CBT vs EAC, > 10% CBT vs WLC
Selective reporting (re- porting bias)	High risk	Trial pre-registered (ACTRN012606000124538). Most outcomes included in the manuscript. Additional secondary outcomes included in paper.
Treatment expectations	Low risk	Treatment credibility used for CBT and EAC groups: no difference

#### Parker 1988

#### Study characteristics

Methods	RCT; 3 arms; assessed pre-treatment, 6 months, 1 year	
Participants	End of treatment n = 83	
	Start of treatment n = not given	
	Sex: 3 F, 80 M	
	Mean age = 60.6 (SD 7.7)	
	Source = hospital	
	Diagnosis = rheumatoid arthritis	
	Mean years of pain = 11.4	
Interventions	"cognitive behavioural pain management group"	



## Parker 1988 (Continued) "attention placebo group" "control group" (TAU) Outcomes Primary pain outcome: no data available Primary disability outcome: no data available Primary distress outcome: no data available Visual analogue scale pain McGill Pain Questionnaire pain dimensions **Coping Strategies Questionnaire** Arthritis Impact Measurement Scale (AIMS) Beck Depression Inventory Symptom Checklist-90R psychological symptoms Hassles Scale Ways of Coping Questionnaire Arthritis Helplessness Index Disease status measures, including walking speed Notes Funding statement: "Supported in part by the Medical Research Service of the Veterans Administration and by a Multipurpose Arthritis Center grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (DHHS 2 P60 AR-20658-09)." Conflict of interest statement: None included in paper No data provided

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"using a table of random numbers, subjects were assigned"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition not reported, nor description of how the authors would deal with missing data
Selective reporting (re- porting bias)	Unclear risk	Outcomes partially reported; trial not pre-registered
Treatment expectations	Low risk	Treatment credibility assessed and no significant differences identified be- tween the two groups



## Pincus 2015

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, 3-, 6-months		
Participants	Post-treatment (3 months) n = 65		
	Start of treatment n = 89		
	Sex: 54 F, 35 M		
	Mean age = 44.6 (SD 16.0)		
	Source = referrals from musculoskeletal or physiotherapy units		
	Diagnosis = chronic low back pain		
	Mean years of pain = 3.6 (SD 3.0)		
Interventions	CCBT "Contextual cognitive behavioural therapy"		
	"Physiotherapy"		
Outcomes	Primary pain outcome: Brief Pain Inventory pain severity		
	Primary disability outcome: Roland & Morris Disability Questionnaire		
	Primary distress outcome: Hospital Anxiety and Depression Scale		
	Tampa Scale for Kinesiophobia		
	Brief Pain Inventory		
	Chronic Pain Acceptance Questionnaire		
	Acceptance and Action Questionnaire		
	Roland & Morris Disability Questionnaire		
	Short Form 12 SF-12 Medical Outcomes Study		
	Hospital Anxiety and Depression Scale		
	EuroQol-5D		
	Modified Patient Global Impression of Change		
	Expectations of and satisfaction with treatment		
Notes	ACT vs AC: analyses 5.1, 5.2, 5.3		
	Trial registration: ISRCTN43733490		
	Funding statement: "This project is funded by Arthritis Research, UK (grant code: 19401) and was en- dorsed by the Clinical Studies Group for Musculoskeletal Pain. NHS service support costs were also se- cured from the Hampshire and Isle of White Comprehensive Local Research Network (the Lead CLRN)."		
	Conflict of interest statement: "The authors declare that they have no competing interests."		
Risk of bias			
Bias	Authors' judgement Support for judgement		

## Pincus 2015 (Continued)

Random sequence genera- tion (selection bias)	Low risk	"This was carried out by remote computerised randomisation, which the re- searcher communicated to patients during the interview"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Telephone interview data collection but not stated by whom
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; methods to deal with missing data not described
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (ISRCTN43733490). All outcomes in registration included in paper
Treatment expectations	Unclear risk	Treatment expectations assessed but not statistically analysed

## Puder 1988

Study characteristics			
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 1 month		
Participants	End of treatment n = 69		
	Start of treatment n = 71		
	Sex: 49 F, 20 M		
	Mean age = 52.7 (SD 14.4)		
	Source = community		
	Diagnosis = mixed chronic pain		
	Mean years of pain = 10.0		
Interventions	"Cognitive behaviour therapy"		
	"waiting list"		
Outcomes	Primary pain outcome: pain diary		
	Primary disability outcome: pain interference		
	Primary distress outcome: none available		
	Pain diary 0 to 5: highest and lowest ratings		
	Pain interference 0 to 5		
	Coping 0 to 5		
	Medication use		



#### Puder 1988 (Continued)

Notes

Funding statement: "This article is based on a doctoral dissertation completed in the Department of Psychology, Washington University, St. Louis, Missouri, and supported, in part, by Training Grant AG 00030 from the National Institute on Aging"

Conflict of interest statement: None included in paper

CBT vs TAU, post-treatment: analyses 2.1, 2.2

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" - no method described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; no description of how missing data were dealt with
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Unclear risk	Not assessed

#### Sattell 2012

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 9-months
Participants	Post-treatment n = 175
	Start of treatment n = 211
	Sex: 139 F, 72 M
	Mean age = 48.0 (SD 11.6)
	Source = hospital psychosomatic outpatients, Germany
	Diagnosis = multi-somatoform disorder, including at least one pain-related symptom
	Mean years of symptoms = 10.6 (SD 5.5)
Interventions	PIT "Psychodynamic interpersonal therapy", brief
	EMC "Enhanced medical care"
Outcomes	Primary pain outcome: none
	Primary disability outcome: SF-36 Physical Component Score



Sattell 2012 (Continued)	
	Primary distress outcome: Patient Health Questionnaire (depression score)
	Short Form Health Questionnaire (SF-36)
	Patient Health Questionnaire PHQ-9
	Whiteley Index Short Form anxiety
Notes	Not analysed: "other"
	Trial registration: ISRCTN23215121
	Funding statement: "The German Research Foundation (DFG; He 3200/4-1) funded this study."
	Conflict of interest statement: "None."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"A computer program generated a blocked randomisation list and the Coordi- nation Centre for Clinical Trials covertly applied this list to our sample"
Allocation concealment (selection bias)	Low risk	"we submitted a randomisation request and the centre returned the result for the patient in question within 24 hours"
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"The patients completed the questionnaires independently and returned them, usually by post"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Multiple imputations used to replace missing data. Attrition > 10%
Selective reporting (re- porting bias)	High risk	Trial pre-registered (ISRCTN23215121). Some secondary outcomes listed in protocol not included in the paper
Treatment expectations	Unclear risk	Not assessed

## Scheidt 2013

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# **Study characteristics**

Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 12-months
Participants	Post-treatment n = 40 (at 12 months, n < 20 both groups)
	Start of treatment n = 47
	Sex: 47 F, 0 M
	Mean age = 48.8 (SD 7.9)
	Source = hospital and community
	Diagnosis = fibromyalgia
	Mean years of symptoms = 8.1 (SD 7.9)



Scheidt 2013 (Continued)			
Interventions	ASTPP "short-term psychodynamic psychotherapy"		
	TAU "primary care management" (described as active control)		
Outcomes	Primary pain outcome: none		
	Primary disability outcome: Fibromyalgia Impact Questionnaire		
	Primary distress outcome: Hospital Anxiety & Depression Scale		
	Fibromyalgia Impact Questionnaire FIQ		
	Pain Disability Index PDI for pain-related disability		
	Hospital Anxiety & Depression Scale		
	MOS Short Form SF-36 for health-related quality of life		
	Symptom Checklist SCL-27 for psychological distress		
	SOMS-7 for functional physical symptoms		
	Health care use		
Notes	Not analysed: "other"		
	Trial registration: none		
	Funding statement: "Supported as part of an Interdisciplinary Research Project by the Freiburg Insti- tute of Advanced Studies, FRIAS."		
	Conflict of interest statement: none.		
Risk of bias			

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"Patients were randomized in blocks of 10 either to the treatment group or to the control condition according to a 1:1 schedule made beforehand." No method described
Allocation concealment (selection bias)	Low risk	"Information about eligible patients was sent to a study coordinator who had no contact with the patients and was not involved in either intervention. She independently randomized the patients and sent the result of the randomiza- tion back to the clinical coordinator, who initiated the respective intervention"
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	No information about outcome assessment except that it was not therapists who provided treatment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition > 10%; intention to treat analysis on 46 patients. " Missing values of individual items of scales were replaced according to missing replacement procedure of respective inventories"; for other values imputation procedures used
Selective reporting (re- porting bias)	Unclear risk	Trial not registered
Treatment expectations	Unclear risk	Not assessed



# Sharpe 2012

Study characteristics			
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment, 6-months		
Participants	Post-treatment n = 98		
	Start of treatment n = 1	104	
	Sex: 81 F, 23 M		
	Mean age = 56.3 (SD 13.0)		
	Source = hospital and community		
	Diagnosis = rheumatoid arthritis		
	Mean years of illness = 13.6 (14.9)		
Interventions	CBT "Cognitive behavio	oural therapy"	
	BT "Behavioural therap	py"	
	CT "Cognitive therapy"	,	
	WLC "Wait-list control"		
Outcomes	Primary pain outcome: none		
	Primary disability outcome: Health Assessment Questionnaire		
	Primary distress outcome: Hospital Anxiety and Depression Scale depression subscale		
	Hospital Anxiety and Depression Scale		
	Health Assessment Questionnaire for disability		
	Ritchie Articular Index for swollen and tender joint counts		
	Erythrocyte sedimentation rate for disease activity		
	C-reactive protein for disease activity		
Notes	CBT vs TAU, post-treatment and follow-up: 2.2, 2.3, 2.5, 2.6		
	BT vs TAU: analyses 7.2, 7.3, 8.2, 8.3		
	Funding statement: "This study was supported by a grant from the National Health and Medical Re- search Council of Australia (grant No: 211151). L. Sharpe is supported by a senior NHMRC research fel- lowship."		
Conflict of interest statement: "We have no conflicts of interest."		tement: "We have no conflicts of interest."	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Patients were randomly allocated to treatment groups by simple randomiza- tion that was determined according to a standard table of random numbers generated by the Bernoulli function"	
Allocation concealment (selection bias)	Low risk	"Randomization was concealed until after assessmentAfter a participant completed the pre-treatment assessment, a researcher not involved in the as-	



#### Sharpe 2012 (Continued)

		sessment gave each participant a consecutive numberand revealed the treat- ment to which the participant had been randomized. Randomization was con- cealed until after assessment."
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"All assessors remained blind to the allocation throughout the intervention and follow-up"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%. "All analyses were conducted using an intention-to-treat analysis, using the last-observation-carried-forward method."
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Unclear risk	Not assessed

#### Sleptsova 2013

Study characteristics	
Methods	RCT; 2 arms; assessed pretreatment, post-treatment, 12-months
Participants	Post-treatment n = 78
	Start of treatment n = 116
	Sex: 54 F, 24 M
	Mean age = 43.9 (SD 7.3)
	Source = clinics and hospitals
	Diagnosis = mixed chronic pain conditions
	Mean years of pain = 5
Interventions	CsCBT "Culturally sensitive cognitive behavioural therapy"
	CsET "Culturally sensitive exercise treatment"
Outcomes	Primary pain outcome: Visual analogue scale pain intensity
	Primary disability outcome: Pain Disability Index
	Primary distress outcome: General Health Questionnaire
	Visual analogue pain intensity scale
	Short Form 36 SF-36
	General Health Questionnaire GHQ for psychological symptoms
	Pain Disability Index PDI
	Interview of Clinical Symptoms SICS-R
	Pain drawings
	Health care utilisation cost collected retrospectively

# Sleptsova 2013 (Continued)

Notes

No data provided

Funding statement: "The study was financed by Swiss National Funding Programme "Chronic Musculoskeletal Pain"."

Conflict of interest statement: None included in paper

# **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"A computer-generated randomisation list was drawn up for each gender by a statistician of the Basel Institute of Clinical Epidemiology. Details of the series were not known to any of the investigators"
Allocation concealment (selection bias)	Low risk	"Allocation concealment was guaranteed through sequentially numbered, opaque, sealed envelopes enclosing assignments. The envelopes were handed over to the research psychologist after intake interviews were completed"
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	"All initial and follow-up interviews were conducted by a research psychologist not involved in the treatment. Blinded assessments were not feasible for fol- low-up meetings because patients inevitably relayed information about their treatment experiences to the research psychologist"
Incomplete outcome data (attrition bias) All outcomes	High risk	Missing data methods not described ("Intention-to-treat analyses were not performed owing to lack of significant effects"). Attrition > 30%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

#### Smeets 2006

Study characteristics		
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment, 1 year	
Participants	End of treatment n = 212	
	Start of treatment n = 223	
	Sex: 106 F, 117 M	
	Mean age = 41.6 (SD 10.0)	
	Source = pain or rehabilitation clinic	
	Diagnosis = CLBP	
	Mean years of pain = 4/6	
Interventions	"Cognitive behavioural therapy + active physical treatment"	
	"Cognitive behavioural therapy"	
	"active physical treatment"	



Smeets 2006 (Continued)			
	"waiting list"		
Outcomes	Primary pain outcome: MPQ PRI (follow-up only)		
	Primary disability outcome: Roland & Morris Disability Scale		
	Primary distress outcome: BDI		
	Roland Morris Disability Questionnaire disability		
	Difficulty with 3 most limited activities: 0 to 100		
	Visual analogue scale pain		
	Beck Depression Inventory		
	Pain Cognitions List: catastrophising, pain control subscales as process measures		
	Follow-up only		
	MPQ PRI		
	5-minute walk		
	50-foot walk		
	Timed stand-to-sits		
	Extended reach		
	Stair climb		
	Lifting task		
Notes	Trial registration: ISRCTN22714229		
	Funding statement: "This study is supported by Zorgonderzoek Nederland/Medische Wetenschappen (ZonMw) grant number 014-32-007 and the Rehabilitation Centre Blixembosch."		
	Conflict of interest statement: "The author(s) declare that they have no competing interests."		
	1-year follow-up Smeets 2008; December 2009 search		
	CBT plus active PT vs active PT (AC): analyses 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	GA plus problem solving vs TAU: analyses 2.1, 2.2, 2.3 (waiting list not followed up)		

#### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"For each rehabilitation centre a randomization list was generated by computer under supervision of an independent statistician"
Allocation concealment (selection bias)	Low risk	Generated by independent statistician; sealed envelopes
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessment by blinded research assistants
Incomplete outcome data (attrition bias) All outcomes	Low risk	"If data on outcome measures were missing, the baseline-value-carried-for- ward method was used and a worst case analysis by imputing the tenth per-



Unclear risk

#### Smeets 2006 (Continued)

**Treatment expectations** 

		centile score of the outcome measure at post-treatment of the respondents was performed as well." Attrition < 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (ISRCTN22714229) and all outcomes in protocol reported in manuscript

Not assessed

#### Somers 2012

Study characteristics	
Methods	RCT; 4 arms; assessed pre-treatment, post-treatment, 6-, 12- 24-months
Participants	Post-treatment n = 188
	Start of treatment n = 232
	Sex: 184 F, 48 M
	Mean age = 58.0 (SD 10.4)
	Source = Rheumatology, Orthopedic Surgery, Internal Medicine, Family Medicine, and Pain Manage- ment clinics at Duke University Medical Center (DUMC), through flyers posted in the community and from advertisements in local newspapers. Most (90%) participants were recruited through the com- munity and from advertisements in local newspapers, and 10% were recruited from DUMC clinics via physician referral.
	Diagnosis = osteoarthritis knee
	Mean years of pain = Not stated
Interventions	PCST "Pain coping skills training"
	PCST + BWM "PCST + behavioural weight loss"
	BWM-only "Behavioural weight loss"
	"Standard care"
Outcomes	Primary pain outcome: Arthritis Impact Measurement Scales pain subscale
	Primary disability outcome: Arthritis Impact Measurement Scales disability subscale
	Primary distress outcome: Arthritis Impact Measurement Scales psychological subscale
	Arthritis Impact Measurement Scales AIMS (pain, disability, psychological subscales)
	Western Ontario and McMaster (WOMAC) Osteoarthritis Index for pain, stiffness, physical function
	Gait velocity
	Catastrophizing Scale of Coping Strategies Questionnaire CSQ
	Arthritis Self-Efficacy Scale
	Weight Efficacy Life-Style Questionnaire
	Body Mass Index BMI
	Adverse events

# Somers 2012 (Continued)

Notes

CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

Funding statement: "This publication was made possible by grant number P01 AR50245 from the National Institutes of Health."

Conflict of interest statement: "No conflict of interest is reported by the authors."

## **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"a data technician unfamiliar with the research protocol used a random allo- cation computer software program to assign participants in blocks (minimum = 27, maximum = 39) to 1 of 4 treatment conditions"
Allocation concealment (selection bias)	Unclear risk	"A research assistant communicated randomization results to participants." Method unclear
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Post-treatment assessments were conducted by research assistants who were blind to the participant's treatment condition"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"All analyses adhered to the intent-to-treat principle." Mixed models used so no substitution for missing data required. Attrition > 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

#### Strauss 1986

Study characteristics	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months
Participants	End of treatment n = 43
	Start of treatment n = 57
	Sex: 46 F, 11 M
	Mean age = 54.0 (SD 13.0)
	Source = rheumatology clinic
	Diagnosis = rheumatoid arthritis
	Mean years of pain not given
Interventions	"group psychotherapy"
	"relaxation/assertion"
	"no treatment"
Outcomes	Primary pain outcome: no data available

Strauss 1986 (Continued)	
	Primary disability outcome: no data available
	Primary distress outcome: no data available
	4 aggregate outcome measures:
	Functional status, social adaptation, psychological adaptation, psychological symptoms
	Measures contributing to these:
	Arthritis Impact Measurement Scale (AIMS)
	Short Form 36
	Rathus Assertive Behavior Scale
	Rosenberg Self-Esteem Scale
	Hostility Inventory
	Wright's Human Service Scale & Handicap Problems Inventory
Notes	Funding statement: None included in paper
	Conflict of interest statement: None included in paper
	No data provided

#### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" - method not described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Completer analysis conducted;, attrition > 10%.
Selective reporting (re- porting bias)	High risk	Outcomes partially reported; trial not pre-registered
Treatment expectations	Unclear risk	Not assessed

# Tavafian 2011

Study characteristics	
lethods	RCT; 2 arms; assessed pre-treatment, post-treatment (3 months), 6-months
Participants	Post-treatment n = 189
	Start of treatment n = 197
<sup>v</sup> articipants	

avafian 2011 (Continued)		
	Sex: 154 F, 43 M	
	Mean age = 45.3 (SD 10.8)	
	Source = rheumatology clinic, Iran	
	Diagnosis = chronic low back pain	
	Mean years of pain = 6.8 (SD 7.5)	
Interventions	Intervention: "Multidisciplinary rehabilitation program" and visits to rheumatology and drug prescrip tions	
	Control: "Education control" phone consultation with psychologist and visits to rheumatology and drug prescription	
Outcomes	Primary pain outcome: SF-36 bodily pain scale Primary disability outcome: Ronald-Morris Disability Questionnaire	
	Primary distress outcome: SF-36 mental health scale	
	Short-form Health Survey SF-36	
	Ronald-Morris Disability Questionnaire	
	Quebec Back Pain Disability Scale	
Notes	CBT vs AC, post-treatment: 1.1, 1.2, 1.3	
	Trial registration: NCT00600197	
	Funding statement: "This study was funded by research deputy of Tehran University of Medical Sciences, Tehran, Iran."	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"Participants were randomly assigned into the intervention or control group through random permutation blocking of every 6 participants." Method of randomisation not further de- scribed.
Allocation concealment (selection bias)	Unclear risk	"The sequence of allocation was concealed to the rheumatologist who select- ed the eligible patients." Method not described
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	The physician and statistical analyst were blinded to the group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Completer analysis conducted; attrition < 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (NCT00600197). All outcomes included in registration were included in the paper
Treatment expectations	Unclear risk	Not assessed



#### Thieme 2003

Study characteristics	
Methods	RCT; 2 arms; assessed pre-treatment, post-treatment, 6 months, 15 months
Participants	End of treatment n = 61
	Start of treatment n = 83
	Sex: 61 F, 0 M
	Mean age = 47.3 (SD 8.3)
	Source = hospital for rheumatic disorders
	Diagnosis = fibromyalgia
	Mean years of pain = 16.5
Interventions	"operant treatment"
	"standard physical treatment"
Outcomes	Primary pain outcome: MPI pain
	Primary disability outcome: MPI interference
	Primary distress outcome: MPI affective distress
	Diary pain intensity
	Multidimensional Pain Inventory (MPI): pain
	MPI: interference
	MPI: life control
	MPI: affective distress
	MPI: social support
	MPI: self efficacy
	MPI: punishing responses, solicitous responses, distracting responses
	MPI: total activities
	Doctor visits (from medical records)
	Hospital days (from medical records)
	Sleep hours diary
	Medication diary
	Tübingen Pain Behaviour Scale
Notes	BT vs AC: analyses 3.1, 3.2, 3.3, 3.4, 3.5, 3.6
	Funding statement: None included in paper
	Conflict of interest statement: None included in paper



# Thieme 2003 (Continued)

# **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" - method not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; no description of how missing data were handled
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Unclear risk	Not assessed

#### Thieme 2006

Study characteristics	5
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6-, 12-months
Participants	Post-treatment n = 100
	Start of treatment n = 125
	Sex: 125 F, 0 M
	Mean age = (SD)
	Source =10 outpatient rheumatological clinics
	Diagnosis = fibromyalgia
	Mean years of pain = not stated
Interventions	OBT "Operant behavioural"
	CBT "Cognitive behavioural therapy"
	AP "Attention-placebo treatment"
Outcomes	Primary pain outcome: Multidimensional Pain Inventory pain severity
	Primary disability outcome: Fibromyalgia Impact Questionnaire
	Primary distress outcome: MPI distress
	Blood chemistry analysis
	Neurological examination



Thieme 2006 (Continued)	
	Evaluation of tender points
	Fibromyalgia Impact Questionnaire
	West Haven-Yale Multidimensional Pain Inventory
	Pain-Related Self-Statements Scale
	Satisfaction with treatment
	Tübingen Pain Behaviour Scale
	Health care utilisation
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6
	BT vs AC: analyses 3.1, 3.2, 3.3, 3.4, 3.5, 3.6
	Funding statement: "This study was supported by grants from the Deutsche Forschungsgemeinschaft to KT (Th 899-1/2 and 899-2/2) and HF (FL 156/26, Clinical Research Unit 107 'Learning, plasticity and pain'), the Max-Planck Award for International Cooperation to HF, and the National Institutes of Health/ National Institute of Arthritis and Musculoskeletal and Skin Diseases to DCT (AR44724 and AR 47298)."
	Conflict of interest statement: "The authors declare that they have no competing interests."

Conflict of interest statement: "The authors declare that they have no competing interests."

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	Method of randomisation not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	LOCF analyses used to handle missing data; attrition > 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	Treatment expectations did not differ between groups
Treatment expectations	Low risk	Treatment expectations did not differ between groups

#### **Thorn 2011**

Study characteristics	5	
Methods	RCT; 2 arms; assessed	
	pre-treatment, post-treatment, 6 months	
Participants	Post-treatment n = 61	
	Start of treatment n = 83	



Blinding of outcome as-

All outcomes

sessment (detection bias)

Trusted evidence. Informed decisions. Better health.

Thorn 2011 (Continued)			
	Sex: 65 F, 18 M		
	Mean age = 52.8 (SD 13	.2)	
	Source = health clinics	and community, low literacy rural population, USA	
	Diagnosis = mixed chro	nic pain conditions	
	Mean years of pain = no	bt stated	
Interventions	CBT "Cognitive behavio	oural therapy" group, 15hours	
	EDU "Education" group	o, 15hours	
Outcomes	Primary pain outcome	e: Brief Pain Inventory pain severity	
	Primary disability out	come: Roland-Morris Disability Scale-11 item	
	Primary distress outc	ome: Center for Epidemiological Studies Depression Scale	
	Brief Pain Inventory BPI pain severity, pain interference		
	Roland-Morris Disability Scale-11 item		
	Pain Catastrophizing Scale PCS		
	Center for Epidemiological Studies Depression Scale CES-D		
	Quality of Life Scale for life satisfaction		
	Treatment credibility		
	Client Satisfaction Questionnaire-8		
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
		his research was supported by the National Institute of Nursing Research and of Mental Health, NR010112."	
	Conflict of interest statement: "The authors have no conflicts of interest to report."		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Randomization was generated by consecutive coin toss by a graduate re- search assistant to assign participant numbers (starting at 101) to either CBT or EDU conditions."	
Allocation concealment (selection bias)	Low risk	"The assignment for each participant number was recorded on a slip of paper and concealed in an envelope"; envelope opened after pre-treatment assess- ment.	

Incomplete outcome dataUnclear risk"Missing data were imputed using the multiple imputation algorithm from<br/>PRELIS 2.54." Attrition > 10%All outcomesAll outcomes

tant not involved in treatment delivery"

"All assessments were completed in person, face-to-face by a research assis-

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Low risk



Thorn 2011 (Continued)		
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	No differences between groups on treatment expectations

#### **Thorn 2018**

Study characteristics			
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6-months		
Participants	Post-treatment n = 241		
	Start of treatment n = 290		
	Sex: 205 F, 85 M		
	Mean age = 50.6 (SD 8.9)		
	Source = clinics		
	Diagnosis = mixed chronic pain conditions		
	Mean years of pain = 16.6 (SD 12.2)		
Interventions	CBT "Cognitive behavioural therapy, learning about my pain"		
	EDU "Education, learning about my pain"		
	"Usual care"		
Outcomes	Primary pain outcome: Brief Pain Inventory-Short Form pain intensity		
	Primary disability outcome: Brief Pain Inventory-Short Form pain interference		
	Primary distress outcome: Patient Health Questionnaire-9		
	Brief Pain Inventory-Short Form (pain intensity, pain interference)		
	Patient Health Questionnaire-9		
	Adverse events		
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6		
	CBT vs TAU, post-treatment and follow-up: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6		
	Trial registration: NCT01967342		
	Funding statement: "Funded partially by a PCORI Research Award (contract 941) and partially by the University of Alabama"		
	Conflict of interest statement: "Dr. Thorn reports grants from PCORI and indirect costs recovery for re- search expenses from the University of Alabama during the conduct of the study and personal fees from Guilford Publications outside the submitted work. Drs. Eyer and Burns, Mr Van Dyke, Ms. Newman, and Mr Penn report grants from PCORI during the conduct of the study. Dr Campbell reports grants from the University of Alabama and PCORI during the conduct of the study. Dr Cheavens reports per- sonal fees from the University of Alabama during the conduct of the study. Authors not named here have disclosed no conflicts of interest."		



#### Thorn 2018 (Continued)

# **Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"The study statistician used statistical software to generate a random-number table that stratified treatment assignments by site and was balance by treat- ment group"
Allocation concealment (selection bias)	Unclear risk	No description
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Study outcomes were collected by blinded, trained assessors"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data imputed using 'missing at random' technique; attrition > 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (NCT01967342). Outcomes outlined in the protocol matched those in the manuscript.
Treatment expectations	Unclear risk	Not assessed

#### Thorsell 2011

Study characteristics		
Methods	RCT; 2 arms; self-help acceptance and commitment therapy, self-help applied relaxation; assessed post-treatment: 6-month and 12-month follow-up	
Participants	End of treatment: n = 64	
	Start of treatment: n = 98	
	Sex: 63 F; 35 M	
	Source = pain clinic	
	Diagnosis = mixed chronic pain	
	Mean age: 46.0 (SD 12.3)	
	Mean years of pain: not given (98% more than 1 year)	
Interventions	Self-help acceptance and commitment therapy; self help applied relaxation	
Outcomes	Primary pain outcome: pain intensity 0 to 10	
	Primary disability outcome: OMPQ 5 items	
	Primary distress outcome: Depression HADS	
	Pain intensity 0 to 10	
	Function: 5 items 0 to 10 from Orebro Musculoskeletal Pain Questionnaire (reverse direction)	
	Depression HADS	

Thorsell 2011 (Continued)	Anxiety HADS	
	Satisfaction With Life Scale	
	Chronic Pain Acceptance Questionnaire	
Notes	Funding statement: None included in paper	
	Conflict of interest statement: None included in paper	
	ACT vs aAC: analyses 5.1, 5.2, 5.3, 5.4, 5.5, 5.6	
	2011 update search	

# **Risk of bias**

Bias	Authors' judgement	Support for judgement
DIdS	Authors' Judgement	Support for Judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomized by drawing pieces of paper with type of intervention" - not clear if this truly randomised
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Mixed Model Repeated Measures were used to conduct iITT analyses; attrition > 10%
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered
Treatment expectations	Low risk	Treatment credibility assessed and no significant differences were identified between groups

#### Turner 1988

Study characteristics	'S	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months, 1 year	
Participants	End of treatment n = 53	
	Start of treatment n = 81	
	Sex: 30 F, 51 M	
	Mean age = 46.0 (SD not given)	
	Source = pain or rehabilitation clinic	
	Diagnosis = chronic low back pain	
	Mean years of pain = 6.2	
Interventions	"CBT"	



#### Turner 1988 (Continued)

<b>Turner 1988</b> (Continued)	"operant behavior therapy"
	"waiting list"
Outcomes	Primary pain outcome: MPQ PRI
	Primary disability outcome: SIP patient-rated
	Primary distress outcome: Cognitive Errors Questionnaire
	Multidimensional Pain Questionnaire: Pain Response Index
	Sickness Impact Profile: patient-rated
	Sickness Impact Profile: spouse-rated
	Pain behaviour (Keefe & Block) observation
	Pain Behavior Checklist patient-rated
	Pain Behavior Checklist spouse-rated
	Cognitive Errors Questionnaire
Notes	Funding statement: "This research project was supported by Grants 1 RO1 NS19619 and PO1 NS16329 from the National Institute of Neurological and Communicative Disorders and Stroke and by National Institutes of Health Biomedical Research Grant RR05432."
	Conflict of interest statement: None included in paper
	CBT vs TAU, post-treatment (waiting list not followed up): analyses 2.1, 2.2
	BT vs TAU, post-treatment (waiting list not followed up): analyses 4.2
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" - method not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; no description of how missing data were handled
Selective reporting (re- porting bias)	Unclear risk	Partially reported but full account of excluded measures. Trial not pre-regis- tered.
Treatment expectations	Low risk	Treatment expectations assessed: no differences between groups identified



#### Turner 2006

# Study characteristics

Methods	RCT; 2 arms; assessed	pre-treatment, post-treatment, 6 months, 1 year	
Participants	End of treatment n = 142		
	Start of treatment n = 1	158	
	Sex: 128 F, 30 M		
	Mean age = 37.4 (SD 11	.3)	
	Source = pain or rehabilitation clinic		
	Diagnosis = temporomandibular joint pain		
	Mean years of pain = not given		
Interventions	"brief CBT: Pain Manag	ement Training"	
	"education/attention o	control: Self care control"	
Outcomes	Primary pain outcom	e: Graded Chronic Pain Scale: Pain Intensity	
	Primary disability outcome: none available		
	Primary distress outcome: BDI depression		
	Graded Chronic Pain Scale: Activity Interference		
	Graded Chronic Pain Scale: Pain Intensity		
	Beck Depression Inventory (BDI)		
	Mandibular Function Impairment Questionnaire (MFIQ)		
	Survey of Pain Attitudes (SOPA)		
	TMD self efficacy scale		
	CSQ catastrophising subscale		
	Pain Catastrophizing Scale rumination subscale		
	Chronic Pain Coping Inventory (CPCI) task persistence, coping self statements, relaxation, rest		
Notes	Funding statement: "Funding for this study was provided by the National Institute of Dental and Cran- iofacial Research Grant P01 DE08773."		
	Conflict of interest statement: None included in paper		
	CBT vs AC, post-treatment and follow-up: analyses 1.1, 1.3, 1.4, 1.6		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Randomization assignments were generated by a biostatistician (LM) using randomly selected block sizes of two or four using the sample function of the S-PLUS statistical software (Insightful Corporation, Seattle, WA) to prevent de termination of the treatment assignment."	

Turner 2006 (Continued)		
Allocation concealment (selection bias)	Low risk	"Treatment assignments were recorded on slips of paper numbered consec- utively within each stratum and sealed in envelopes sequentially numbered by stratum. Randomization assignment was concealed to all study personnel until envelopes were opened by research staff after subject consent was ob- tained."
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition fully reported; no test for differences "imputation of the missing val- ues, which used a Markov Chain Monte Carlo (MCMC) method, assuming an ar- bitrary missing data pattern and multivariate normality and a single chain to create five imputations using 200 burn-in iterations before the first imputation and 100 iterations between imputations" Attrition = 10%.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Unclear risk	Treatment credibility assessed:credibility in treatment group significantly higher than the control group

# van Eijk 2013

Study characteristics	5
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, and 21-24-months
Participants	Post-treatment n = 203 completed assessments
	Start of treatment n = 203
	Sex: 195 F, 8 M
	Mean age = 41.8 (SD 9.6)
	Source = outpatient rheumatology clinics
	Diagnosis = fibromyalgia
	Mean years of pain = 6.8 (SD 6.3)
Interventions	MD "Multidisciplinary intervention with after-care": psychological therapy, physiotherapy, sociothera- py, education
	AE "Aerobic exercise", group gym sessions with physiotherapist
	UC "Usual care": individual education and psychological support or other treatment as necessary
Outcomes	Primary pain outcome: Fibromyalgia Impact Questionnaire pain single item
	Primary disability outcome: Fibromyalgia Impact Questionnaire physical functioning single item
	Primary distress outcome: Fibromyalgia Impact Questionnaire depression single item
	EuroQol (EQ-5D) for health-related quality of life
	Participants report participation in activities, self-developed

van Eijk 2013 (Continued)	Fibromyalgia Impact Questionnaire Health care utilisation
Notes	CBT vs AC, post-treatment: 1.1, 1.2, 1.3
	Trial registration: ISRCTN32542621
	Funding statement: "The study was supported by Maastricht University Medical Centre and by Care Re- newal Grants of medical insurance companies in the region."
	Conflict of interest statement: "None"

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Randomisation was performed using computer-generated random numbers in opaque, sealed envelopes, following the order of consent to participate in the observational study"
Allocation concealment (selection bias)	Low risk	"Randomisation was performed using computer-generated random numbers in opaque, sealed envelopes, following the order of consent to participate in the observational study"
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data deemed to be missing at random. Attrition < 10% although of the 108 as- signed to MD, 67 started and 60 completed; of 47 assigned to AE, 19 started and 8 completed.
Selective reporting (re- porting bias)	High risk	Trial pre-registered (ISRCTN32542621). Primary and secondary outcomes out- lined in registration not all reported in paper.
Treatment expectations	Unclear risk	Not assessed

# Van Koulil 2010

# Study characteristics

Methods	RCT; 2 arms; CBT: WLC; assessed post-treatment: 6-month follow-up
Participants	End of treatment: n = 152
	Start of treatment: n = 158
	Sex: 148 F, 10 M
	Mean age: 40.8 (SD 10.5)
	Source = rheumatology clinics
	Diagnosis = fibromyalgia
	Mean years of pain: not given (< 5 years since diagnosis)



#### Van Koulil 2010 (Continued)

Interventions	Tailored CBT with exercise training; waiting list control
Outcomes	Primary pain outcome: Pain IRGL
	Primary disability outcome: Mobility IRGL
	Primary distress outcome: Negative mood IRGL
	Pain: 6 items of IRGL
	Disability: 7 mobility items of IRGL (reversed)
	Impact: Fibromyalgia Impact Questionnaire
	Negative mood: 6 items of IRGL
	Anxiety: 10 items of IRGL
Notes	Trial registration: NCT00268606
	Funding statement: "Partially supported by grants from the Dutch Arthritis Association and The Nether- lands Organization for Health Research and Development."
	Conflict of interest statement: None included in paper
	CBT vs TAU: analyses 2.1, 2.2, 2.3, 2.4, 2.5, 2.6
	2011 update search
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomized in clusters" - method not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	LOFC analyses completed; attrition < 10%
Selective reporting (re- porting bias)	High risk	Trial pre-registered (NCT00268606). Outcomes listed in registration do not match those in the manuscript.
Treatment expectations	Unclear risk	Not assessed

#### Vitiello 2013

 Study characteristics

 Methods
 RCT; 3 arms; assessed pre-treatment, post-treatment (2 months), 9-months



<b>itiello 2013</b> (Continued)			
Participants	Post-treatment n = 354		
	Start of treatment n = 3	367	
	Sex: 288 F, 79 M		
	Mean age (minimum 60	Dy) = 73.1 (SD 8.2)	
	Source = health mainte	enance organisation, US	
	Diagnosis = osteoarthr	itis	
	Mean years of pain = no	ot stated	
Interventions	CBT-PI "Cognitive beha	avioural therapy for pain and insomnia"	
	CBT-P "Cognitive beha	vioural therapy for pain"	
	EOC "Education"		
Outcomes	Primary pain outcom	e: Chronic Pain Scale pain severity	
	Primary disability outcome: none		
	Primary distress outcome: Geriatric Depression Scale		
	Insomnia Severity Index 7 items, 0-5, 5 is worst		
	Chronic Pain Scale,		
	Sleep efficiency (actiwatch)		
	Arthritis Impact Measurement Scales AIMS V2, short form, revised, arthritis symptom subscale		
	Geriatric Depression Scale		
	Medication use, analge	esics and hypnotics	
Notes	CBT vs AC, post-treatment and follow-up: 1.1, 1.3, 1.4, 1.6		
	Trial registration: NCT01142349		
	Funding statement: "The study was supported by Public Health Service Grant R01-AG031126, Cognitive Behavioral Therapy for Arthritis Pain and Insomnia in Older Adults, Drs. Vitiello (lead), McCurry, and Von Korff, multiple principal investigators."		
	Conflict of interest statement: "The editor in chief has reviewed the conflict of interest checklist provid- ed by the authors and has determined that the authors have no financial or any other kind of personal conflicts with this paper."		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	"Using a computer algorithm, the project programmer randomly assigned sets of nine groups to the three experimental conditions in one block of three groups and one block of six groups to balance assignments across the six par- ticipating primary care clinics"	
Allocation concealment	Unclear risk	Not described	

Allocation concealment Unclear risk Not described (selection bias)



#### Vitiello 2013 (Continued)

Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"Assessors were blinded to which of the intervention arms participants were assigned"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%; BOCF in analyses; modified ITT using those who started treat- ment.
Selective reporting (re- porting bias)	Low risk	Protocol published (see Vitiello 2013 reference; NCT01142349). All outcomes in protocol included in paper
Treatment expectations	Unclear risk	Not assessed

# Vlaeyen 1996

Study characteristics	s	
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months, 1 year	
Participants	End of treatment n = 122	
	Start of treatment n = 131	
	Sex: 110 F, 15 M	
	Mean age = 44.0 (SD 9.4)	
	Source = pain or rehabilitation clinic	
	Diagnosis = fibromyalgia	
	Mean years of pain = 10.2	
Interventions	"cognitive + group discussion"	
	"education + group discussion"	
	"waiting list"	
Outcomes	Primary pain outcome: pain intensity score	
	Primary disability outcome: none available	
	Primary distress outcome: BDI depression	
	Composite scores from factor analysis:	
	Pain intensity, pain coping, pain control, relaxation, catastrophising, pain behaviour, activi- ty	
	Measures contributing to factors:	
	Multidimensional Pain Questionnaire: Pain Response Index	
	Coping Strategies Questionnaire (CSQ)	
	Beck Depression Inventory (BDI) (none available)	
	Fear Survey Schedule	
	Arthritis knowledge	
evenological thoranios	for the management of chronic pain (evoluting headache) in adulte (Deview)	120



Vlaeyen 1996 (Continued)	Maudsley Obsessive Compulsive Inventory
	Pain behaviour scale
	Multidimensional Pain Locus of Control Scale (MPCL)
	Walking distance, walking time, cycling time
Notes	Funding statement: None included in paper
	Conflict of interest statement: None included in paper
	CBT vs AC, post-treatment: analyses 1.1, 1.3

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	"randomly assigned" - method not described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 10%, no description of how missing data were handled.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Low risk	Treatment credibility assessed: no significant differences were identified.

#### Wang 2018

Study characteristic	s
Methods	RCT: 2 arms, assessed pre-treatment and post-treatment (3 months)
Participants	End of treatment n = 156
	Start of treatment n = 156
	Sex: 0 F, 156 M
	Mean age = 37.0 (SD 8.2)
	Source = hospital
	Diagnosis = chronic pelvic pain ("prostatitis")
	Mean years of pain = 3.3 (2.1)
Interventions	CBT: psychological intervention (counselling, CBT, relaxation, family support, group discussion) plus routine medication



Vang 2018 (Continued)	Control: routine medication
Outcomes	Primary pain outcome: not reported: item 4 of NIH-CPSI requested from author
	Primary disability outcome: none
	Primary distress outcome: Self-Rating Depression Scale (SDS)
	Overall symptom score: NIH-CPSI - chronic prostatitis symptom index
	Self-rating depression scale (SDS)
	Self-rating anxiety (SAS)
	Internation Index of Erectile Function IIEF-5
	White blood cell count
Notes	CBT vs TAU: 2.2
	Funding statement: no information
	Conflict of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"randomised by computer-generated random number tables"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome as- sessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts
Selective reporting (re- porting bias)	High risk	Primary and secondary outcomes differ in protocol from trial
Treatment expectations	Unclear risk	Not reported

# Wiklund 2018

Study characteristic	s
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6-, 12-months
Participants	Post-treatment n = 200
	Start of treatment n = 299 randomised (232 received allocated treatment)
	Sex: not stated



sessment (detection bias)

Incomplete outcome data

Selective reporting (re-

Treatment expectations

All outcomes

(attrition bias) All outcomes

porting bias)

Trusted evidence. Informed decisions. Better health.

Wiklund 2018 (Continued)			
	Mean age = 54.2 (SD 10	0.2)	
	Source = pain rehab an	nd community advertisements	
	Diagnosis = mixed chro	onic pain conditions	
	Mean years of pain = no	ot stated, minimum 3 months	
Interventions	ACT: "Acceptance & Co	mmitment Therapy-based stress management" with exercise	
	Exercise "Physical exer	rcise"	
	Control: "Active contro	ol", group discussion of pain experience, moderated by staff member	
Outcomes	Primary pain outcome: Pain intensity numeric rating scale		
	Primary disability out	tcome: none	
	Primary distress outc	ome: Hospital Anxiety and Depression Scale	
	Insomnia Severity Inde	ex ISI	
	Pain intensity numeric	rating scale 0-10	
	Hospital Anxiety and D	epression Scale	
Notes ACT vs AC: analyses 5.1, 5.2, 5.4, 5.5		L, 5.2, 5.4, 5.5	
	Trial registration: NCT	02399644	
	Funding statement: "The present study was supported by a grant from the Vårdal Foundation (Rehsam) and the County Council of Östergötland."		
	Conflict of interest statement: "The authors declare that they have no competing interest		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	"A statistician prepared an excel sheet where ten cells for each group were put in random order in the first column. The included participants were then put in the next column consecutively"	
Allocation concealment (selection bias)	Unclear risk	Not described	
Blinding of outcome as-	Unclear risk	Not described. All self-report	

Attrition > 10%; modified ITT analyses used, mixed model analysis.

Trial was pre-registered (NCT02399644). Some outcomes missing in paper

from trial registration and primary outcomes not narrated first in the paper

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Not assessed

Unclear risk

High risk

Unclear risk



## Williams 1996

# **Study characteristics**

Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months, 1 year
Participants	End of treatment n = 99
	Start of treatment n = 121
	Sex: 68 F, 53 M
	Mean age = 50.0 (SD 11.5)
	Source = pain clinic
	Diagnosis = mixed chronic pain, low back commonest
	Mean years of pain = 7.8
Interventions	"inpatient CBT"
	"outpatient CBT"
	"waiting list"
Outcomes	Primary pain outcome: VAS pain
	Primary disability outcome: SIP patient-rated
	Primary distress outcome: BDI depression
	Visual analogue scale (VAS): pain intensity
	Visual analogue scale (VAS): pain distress
	Sickness Impact Profile (SIP): patient-rated
	Beck Depression Inventory (BDI)
	State-Trait Anxiety Inventory (STAI)
	Coping Strategies Questionnaire (CSQ): catastrophising
	Pain Self-Efficacy Questionnaire (PSEQ)
	Pain Cognitions Questionnaire (PCQ)
	Walk distance
	Arm endurance
	Stair climb
	Stand-ups
	Medication use
	Health care use
Notes	Funding statement: "This work was undertaken with a generous grant from the Kings Fund, supple- mented by the Special Trustees of St Thomas' Hosptial and the South East Thames Regional Health Au thority."

Conflict of interest statement: None included in paper



Williams 1996 (Continued)

CBT vs TAU, post-treatment (waiting list not followed up): analyses 2.1, 2.2, 2.3

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	"Randomly assigned by throw of a die"
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	"interviewers and assistants blind to the patients' treatment"
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition > 10%; no description of how missing data were handled.
Selective reporting (re- porting bias)	Unclear risk	Trial not pre-registered.
Treatment expectations	Low risk	Treatment expectations assessed: no significant differences between groups identified

#### Zautra 2008

Study characteristics		
Methods	RCT; 3 arms; assessed pre-treatment, post-treatment, 6 months follow-up	
Participants	Start of treatment n = 142	
	End of treatment n = 137	
	46 M, 97 F	
	Mean age 62.1 men, 50.6 women	
	Diagnosis = rheumatoid arthritis	
	Mean years of rheumatoid arthritis 15.4 years men, 11.6 years women	
	Mean years since diagnosis = 54.2 (SD 13.6)	
Interventions	CBT "cognitive behavioral therapy for pain" with mindfulness and education	
	M "mindfulness meditation and emotion regulation therapy" with education	
	E "education-only group"	
Outcomes	Primary pain outcome: pain diary 0 to 100	
	Primary disability outcome: none	
	Primary distress outcome: PANAS negative affect	
	Pain once-daily diary 0 to 100	



Zautra 2008 (Continued)			
	Positive and Negative Affect Schedule (PANAS): provides positive affect and negative affect scores		
	Depressive symptoms: sum of 6 items		
	Pain coping efficacy (2 items, 1 to 5)		
	CSQ catastrophising subscale		
	Pain control 1 to 10		
	Disease Activity Score from examination of 28 joints by rheumatologist		
	Interleukin IL-6		
Notes	Trial registration: NCT00475111		
	Funding statement: None included in paper		
	Conflict of interest statement: None included in paper		
	Conflict of interest statement: None included in paper December 2009 search		
	December 2009 search		

**Risk of bias** 

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Random numbers table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Assessed by staff not involved in treatment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Multilevel modelling used and assumes data are missing due to collection er- rors or at random; attrition < 10%
Selective reporting (re- porting bias)	Low risk	Trial pre-registered (NCT00475111); outcomes in protocol reported in paper.
Treatment expectations	Unclear risk	Not assessed.

AC: active control; AIMS: Arthritis Impact Measurement Scale; BDI: Beck Depression Inventory; BT: behavioural therapy; CBT: cognitive behavioural therapy; CEQ: Cognitive Errors Questionnaire; CES-D: Center for Epidemiologic Studies Depression Scale; CLBP: chronic low back pain; CSQ: Coping Strategies Questionnaire; DASS: Depression, Anxiety & Stress Scale; EMG: electromyograph; FESV: Pain-Related Distress Questionnaire; FIQ: Fibromyalgia Impact Questionnaire; GA: graded activity; HADS: Hospital Anxiety and Depression Scale; HSCL: Hopkins Checklist; IRGL: Invloed van Reuma op Gezondheid en Leefwijze; MPQ PRI: Melzack Pain Questionnaire Pain Response Index; NRS: numerical rating scale; OMPQ: Orebro Musculoskeletal Pain Questionnaire; PANAS: Positive and Negative Affect Schedule; PCCL: Pain Coping and Cognition List; PCS: Pain Catastrophizing Scale; PDI: Pain Disability Index; PRSS: Pain-Related Self-Statements; PT: physical treatment; RAI: Rheumatoid Arthritis Index; RCT: randomised controlled trial; SD: standard deviation; SIP: Sickness Impact Profile; SLE: systemic lupus erythematosus; SOPA: Survey of Pain Attitudes; TAU: treatment as usual; TSK: Tampa Scale for Kinesiophobia; VAS: visual analogue scale; WHO: World Health Organization; WHYMPI: West Haven Yale Multidimensional Pain Inventory; WLC: waiting list control.



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

Study	Reason for exclusion
Bergdahl 1995	n < 20/arm at post-treatment
Bourgault 2015	Psychologist did not deliver intervention
Broderick 2014	Not an efficacy trial
Cederbom 2019	Insufficient psychotherapeutic content
Chavooshi 2017a	No suitable control for treatment
Chavooshi 2017b	No suitable control for treatment
Dedering 2018	Insufficient psychotherapeutic content
Ehrenborg 2010	No suitable control for treatment
Falcao 2008	Insufficient psychotherapeutic content
Gardiner 2019	Insufficient psychotherapeutic content
Garland 2013	Insufficient psychotherapeutic content
Glombiewski 2018	No suitable control for treatment
Godfrey 2020	Insufficient psychotherapeutic content
Gould 2020	Psychology not of primary interest so no control for treatment
Hammond 2001	Insufficient psychotherapeutic content
Harris 2017	Psychology content not delivered by psychologists
Haugli 2000	Psychological content not delivered by psychologists
Hirase 2018	Insufficient psychotherapeutic content
Jensen 1997	No suitable control for treatment
Jørgensen 2011	Participants did not have chronic pain
Kerns 2014	No suitable control for treatment
Lami 2018	No control for psychological treatment
Leeuw 2008	No suitable control for treatment
Linden 2014	Psychological content not delivered by psychologists
Luciano 2011	Insufficient psychotherapeutic content
Mas 2019	Participants did not have chronic pain



Study	Reason for exclusion
McCarberg 1999	Insufficient psychotherapeutic content
Monticone 2012	Psychological content not delivered by psychologists
Mora 2013	Insufficient psychotherapeutic content
Nicholas 2014	No control group
Niedermann 2012	Psychological content not delivered by psychologists
Overmeer 2016	Insufficient psychotherapeutic content
Pichette-Leclerc 2017	Not RCT
Racine 2018	Insufficient psychotherapeutic content
Schmidt 2011	Insufficient psychotherapeutic content
Siemonsma 2013	Psychological content not delivered by psychologists
Stenstrom 1994	Psychological content not delivered by psychologists
Tejedor 2015	Not RCT
Torres 2018	Insufficient psychotherapeutic content
Turk 1996	Primary aim of treatment was not to reduce pain
Vallabh 2015	Not RCT
Vallejo 2015	N < 20
Verkaik 2014	Psychological content not delivered by psychologists
Vibe Fersum 2013	Psychological content not delivered by psychologists
Wetherell 2011	No suitable control for treatment
Wippert 2020	Insufficient psychotherapeutic content
Woolfolk 2012	Psychological content not delivered by psychologists

# **Characteristics of studies awaiting classification** [ordered by study ID]

# NCT00158275

Methods	3 arms: CBT; behavioural problem-solving therapy; antidepressants
Participants	n = 71 at start;
	Adults with diagnosis of chronic back pain and major depression
Interventions	CBT;



#### NCT00158275 (Continued)

	Behavioural problem-solving therapy;					
	Antidepressants					
Outcomes	Depression PHQ-9					
	Back pain limitations					
	Roland & Morris Disability					
	Beginning and end of treatment and at 6 months					
Notes	Sponsors: Kaiser Permanente, NIMH					
	PI: Michael von Korff					

#### NCT00176163

Methods	2 arms: Operant behavioural treatment vs cannabinoids (THC)						
Participants	n = 240 (estimate)						
	Adults with fibromyalgia and/or back pain						
Interventions	Operant behavioural treatment						
	Cannabinoids (THC)						
Outcomes	Impairment by pain						
	Pain intensity						
	Physical function						
	Emotional state						
	Serious adverse events						
	Subjective rating of improvement, treatment effectiveness, and satisfaction						
Notes	PI: Justus Benrath, Heidelberg University						

# NCT00762125

Methods	4 arms: CBT; exposure therapy; CBT + exposure therapy; attention control						
Participants	n = 266 (estimate) Adults with fibromyalgia						
Interventions	CBT (cognitive restructuring and coping skills training)						
	Exposure therapy						
	CBT + exposure therapy						
	Attention control (support)						



# NCT00762125 (Continued)

Outcomes	Oswestry Disability Index						
	(Further outcomes not listed)						
	Beginning and end of treatment, 1, 3, and 6 months						
Notes	PI: Dennis Turk, University of Washington						
	Sponsors: NIAMS						

## NCT00982410

Methods	2 arms: CBT vs education and support							
Participants	n = 131							
	Veterans with chronic non-cancer pain and substance misuse disorder							
Interventions	CBT							
	Education and support							
Outcomes	Average pain intensity							
	Impact of pain (MPI)							
	Days of alcohol use							
	Days of illicit drug use							
	Pain cold water tolerance							
	Self-efficacy for pain management and physical functioning (CPSS)							
	Beginning of treatment, 3, 6, and 12 months							
Notes	PI: Mark Ilgen, VA Ann Arbor Healthcare System							

# Characteristics of ongoing studies [ordered by study ID]

#### NCT00830011

Study name	Cognitive behavioral therapy for painful diabetic neuropathy
Methods	2 arms: CBT; standard medical care
Participants	n = 80 (estimate)
	Adults with painful diabetic neuropathy
Interventions	CBT
	Standard medical care
Outcomes	Pain intensity
	Pain-related disability (MPI)



## NCT00830011 (Continued)

(continued)	Emotional functioning					
	End of treatment, 24, and 36 weeks					
Starting date	Sep 2004					
Contact information	PI: Robert Kerns, VA Connecticut Healthcare System					
Notes	PI in process of writing up (2019)					

# NCT01993355

Study name	Chronic low back pain: a multidisciplinary approach						
Methods	3 arms: CBT; relaxation; physical exercise						
Participants	n = 66						
	Adults with chronic low back pain						
Interventions	CBT + physical exercise						
	Relaxation + physical exercise						
	Physical exercise						
Outcomes	Quality of life (SF-12)						
	Pain (VAS)						
	Disability (ODI)						
	Life satisfaction						
	Anxiety (STAI)						
	Depression (BDI-13)						
	Sleep (PSQI)						
	Coping						
	Alexithymia (TAS)						
	Stress (PSS-14)						
	Social support (Duke-11)						
	Patient satisfaction						
	Beginning of treatment, 6, and 12 months						
Starting date	Started Mar 2013						
Contact information	PI: Carmina Castellano-Tejedor, Hospital Universitari Vall D'Hebron						
Notes	PI in process of writing up (2019)						

# DATA AND ANALYSES

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1.1 Pain post-treatment	23	3235	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.17, -0.01]
1.2 Disability post-treatment	19	2543	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.20, -0.04]
1.3 Distress post-treatment	24	3297	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.18, -0.00]
1.4 Pain follow-up	16	2362	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.19, 0.04]
1.5 Disability follow-up	15	1919	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.26, 0.02]
1.6 Distress follow-up	16	2362	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.25, -0.01]

# Comparison 1. Cognitive behavioural vs active control at the end of treatment

# Analysis 1.1. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 1: Pain post-treatment

		CBT		Active tr	eatment c	ontrol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	36.9	8.3	56	37.1	10.5	53	3.8%	-0.02 [-0.40, 0.35]	
Carson 2006	14	12.7	60	15	10.4	33	3.1%	-0.08 [-0.51, 0.34]	
Ersek 2008	4.9	1.9	123	5	2.1	101	6.7%	-0.05 [-0.31, 0.21]	_
Greco 2004	1.98	0.87	32	1.97	0.91	33	2.4%	0.01 [-0.48, 0.50]	
Kaapa 2006	3.3	2.5	59	3.4	2.4	61	4.1%	-0.04 [-0.40, 0.32]	
Keefe 1990	4.61	1.73	31	5.67	1.65	35	2.3%	-0.62 [-1.12 , -0.13]	
Keefe 1996	4.21	1.48	28	5.22	2.06	27	2.0%	-0.56 [-1.10 , -0.02]	
Kraaimaat 1995	14.8	4.3	24	15.4	4.6	28	1.9%	-0.13 [-0.68, 0.41]	
Litt 2009	2.7	1.4	52	2.7	1.3	49	3.5%	0.00 [-0.39, 0.39]	
Lumley 2014	2.7	0.7	130	2.7	1.1	134	7.5%	0.00 [-0.24, 0.24]	
Lumley 2017	4.7	1.7	75	5.2	1.7	76	4.9%	-0.29 [-0.61, 0.03]	
Mangels 2009	15.9	5.3	232	16.4	5.8	131	8.9%	-0.09 [-0.31, 0.12]	
Nicholas 2013	4.6	2.1	49	5.3	2.1	53	3.5%	-0.33 [-0.72, 0.06]	
Smeets 2006	42.3	25.6	55	44.6	28.9	52	3.7%	-0.08 [-0.46, 0.30]	
Favafian 2011	-65.8	22.6	92	-56.4	23.6	97	5.8%	-0.40 [-0.69 , -0.12]	
Thieme 2006	3.5	1	42	3.8	1.1	40	2.9%	-0.28 [-0.72, 0.15]	_ <b>_</b> +
Thorn 2011	5.3	2.4	32	4.6	2.3	29	2.2%	0.29 [-0.21, 0.80]	
Thorn 2018	5.4	2.3	83	5.7	2	80	5.3%	-0.14 [-0.45 , 0.17]	
Furner 2006	5.2	1.9	72	5.2	2.1	76	4.9%	0.00 [-0.32, 0.32]	
Vitiello 2013	4.3	3.5	232	4.2	2.9	122	8.6%	0.03 [-0.19, 0.25]	
Vlaeyen 1996	1	1.8	42	0.4	1.8	30	2.5%	0.33 [-0.14, 0.80]	
Zautra 2008	32.5	19.3	51	27.5	18	40	3.2%	0.26 [-0.15 , 0.68]	<b></b>
van Eijk 2013	5.5	2.1	108	5.5	2.1	95	6.2%	0.00 [-0.28, 0.28]	+
Total (95% CI)			1760			1475	100.0%	-0.09 [-0.17 , -0.01]	
Heterogeneity: Tau <sup>2</sup> = (	0.01; Chi <sup>2</sup> = 2	6.81, df =	22 ( $P = 0.2$	22); I <sup>2</sup> = 18%	ò				▼]
Test for overall effect:	Z = 2.14 (P =	0.03)							-2 $-1$ $0$ $1$ $2$
Fest for subgroup diffe	rences: Not a	pplicable							Favours CBT Favours active co

# Analysis 1.2. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 2: Disability post-treatment

		CBT			Active treatment control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	46.2	9.2	56	50.9	9.4	53	4.2%	-0.50 [-0.88 , -0.12]	_ <b></b>
Ersek 2008	11.8	4.9	123	12.4	5.4	101	8.9%	-0.12 [-0.38, 0.15]	
Greco 2004	-52.18	22.88	32	-49.13	26.72	33	2.6%	-0.12 [-0.61 , 0.37]	
Kaapa 2006	20.9	10.1	59	21.6	11.4	61	4.8%	-0.06 [-0.42, 0.29]	
Keefe 1990	2.06	1.29	31	2.34	1.28	35	2.6%	-0.22 [-0.70, 0.27]	
Keefe 1996	1.72	0.71	28	1.53	0.95	27	2.2%	0.22 [-0.31, 0.75]	_ <b>.</b>
Kraaimaat 1995	5.8	5.1	24	10.1	5.7	28	1.9%	-0.78 [-1.35 , -0.21]	
Lera 2009	53.2	13.4	35	57.2	11.3	31	2.6%	-0.32 [-0.80, 0.17]	
Litt 2009	1.5	1.3	52	1.4	1.2	49	4.0%	0.08 [-0.31, 0.47]	
Lumley 2014	1.8	0.6	130	1.8	0.7	134	10.6%	0.00 [-0.24, 0.24]	
Lumley 2017	-37.5	10.1	75	-36.6	8.5	76	6.0%	-0.10 [-0.42, 0.22]	_ <b>_</b>
Mangels 2009	21	13.6	232	21	13.1	131	13.4%	0.00 [-0.21, 0.21]	
Nicholas 2013	10.2	4.9	49	11.4	5.1	53	4.0%	-0.24 [-0.63, 0.15]	
Smeets 2006	11.4	5.3	55	11.9	5.9	52	4.3%	-0.09 [-0.47, 0.29]	
Tavafian 2011	9	5.7	92	10.6	5.8	97	7.5%	-0.28 [-0.56, 0.01]	
Thieme 2006	3.6	2.3	42	4	2.1	40	3.3%	-0.18 [-0.61, 0.25]	
Thorn 2011	8.4	2.8	32	8.6	3.4	29	2.4%	-0.06 [-0.57, 0.44]	
Thorn 2018	5	2.7	83	5.5	2.4	80	6.5%	-0.19 [-0.50, 0.11]	
van Eijk 2013	3.9	3.3	108	3.9	2.1	95	8.1%	0.00 [-0.28, 0.28]	
Total (95% CI)			1338			1205	100.0%	-0.12 [-0.20 , -0.04]	•
Heterogeneity: Tau <sup>2</sup> = 0.00; Chi <sup>2</sup> = 17.32, df = 18 (P = 0.50); l <sup>2</sup> = 0%									
Test for overall effect:									-1 -0.5 0 0.5 1
Test for subgroup differences: Not applicable									Favours CBT Favours active contro

# Analysis 1.3. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 3: Distress post-treatment

	СВТ		Active tr	eatment c	ontrol		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.8	2.5	56	8	1.8	53	3.9%	-0.09 [-0.47 , 0.29]	
Carson 2006	2.9	3.6	60	2.4	2.8	33	3.3%	0.15 [-0.28, 0.57]	_ <u>_</u>
Ersek 2008	11.1	2.9	123	10.9	3.3	101	6.1%	0.06 [-0.20, 0.33]	_
Greco 2004	14.86	10.07	32	16.52	11.53	33	2.7%	-0.15 [-0.64 , 0.34]	
Kaapa 2006	5.5	5.5	59	5.7	5.2	61	4.2%	-0.04 [-0.40, 0.32]	
Keefe 1990	2.59	1.65	31	2.09	0.94	35	2.7%	0.37 [-0.11, 0.86]	
Keefe 1996	1.7	0.97	28	2.48	1.57	27	2.3%	-0.59 [-1.13 , -0.05]	
Kraaimaat 1995	3.1	3.5	24	2.2	2.9	28	2.2%	0.28 [-0.27, 0.83]	
Lera 2009	55.8	9.2	33	58.7	7.4	31	2.6%	-0.34 [-0.84, 0.15]	
Litt 2009	12.8	9.8	52	10.3	8.3	49	3.7%	0.27 [-0.12, 0.66]	
Lumley 2014	2	0.7	130	2.2	0.7	134	6.6%	-0.28 [-0.53 , -0.04]	
Lumley 2017	16.4	11.4	75	18.2	11.2	76	4.9%	-0.16 [-0.48, 0.16]	
Mangels 2009	7	7	232	7.8	7.8	131	7.3%	-0.11 [-0.32, 0.10]	
Nicholas 2013	6.6	7.2	49	9.9	9	53	3.7%	-0.40 [-0.79 , -0.01]	
Smeets 2006	9.1	6.5	54	7.7	6.6	52	3.8%	0.21 [-0.17, 0.59]	
Tavafian 2011	-65.1	21.6	92	-57.7	23.3	97	5.5%	-0.33 [-0.61 , -0.04]	
Thieme 2006	2.8	1.1	42	3.6	1.3	40	3.1%	-0.66 [-1.10 , -0.21]	
Thorn 2011	17.6	12.1	32	17	10	29	2.5%	0.05 [-0.45 , 0.56]	
Thorn 2018	9.1	5.8	83	9.6	6.1	80	5.1%	-0.08 [-0.39, 0.22]	
Turner 2006	8.8	9.3	72	11	10.6	76	4.8%	-0.22 [-0.54, 0.10]	
Vitiello 2013	6.5	9.3	232	6.8	9.1	122	7.2%	-0.03 [-0.25, 0.19]	-
Vlaeyen 1996	13.4	5.8	42	11.9	5.8	30	2.8%	0.26 [-0.21, 0.73]	
Zautra 2008	1.3	0.3	50	1.3	0.3	40	3.4%	0.00 [-0.42, 0.42]	
van Eijk 2013	4.1	3.1	108	4.5	2.8	95	5.8%	-0.13 [-0.41 , 0.14]	
Total (95% CI)			1791			1506	100.0%	-0.09 [-0.18 , -0.00]	
Heterogeneity: Tau <sup>2</sup> = 0	0.02; Chi <sup>2</sup> = 3	5.38, df =	23 (P = 0.0)	)5); I <sup>2</sup> = 35%					×
Test for overall effect:	Z = 2.02 (P =	0.04)							
Test for subgroup diffe	rences: Not a	pplicable							Favours CBT Favours active control

		СВТ			eatment c	ontrol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	40.7	10.9	56	40.5	9.6	53	5.8%	0.02 [-0.36, 0.39]	
Ersek 2008	5	2.1	114	4.5	2.1	103	8.4%	0.24 [-0.03, 0.50]	
Greco 2004	2.05	0.94	32	1.87	0.95	33	4.0%	0.19 [-0.30, 0.68]	
Kaapa 2006	3.3	2.5	53	3.4	2.5	54	5.7%	-0.04 [-0.42, 0.34]	
Keefe 1990	5.22	2.08	30	5.91	1.95	35	4.0%	-0.34 [-0.83, 0.15]	_ <b>-</b> +
Kraaimaat 1995	14.7	4.7	24	16.6	4.6	28	3.3%	-0.40 [-0.95 , 0.15]	_ <b></b> +
Litt 2009	2.1	1.2	52	2.7	1.3	49	5.4%	-0.48 [-0.87 , -0.08]	
Lumley 2014	2.8	1	130	2.8	1.1	134	9.2%	0.00 [-0.24, 0.24]	_
Lumley 2017	4.8	1.7	75	4.9	2	76	7.0%	-0.05 [-0.37, 0.27]	
Mangels 2009	16.6	5.9	232	17.3	6.1	131	10.1%	-0.12 [-0.33, 0.10]	
Smeets 2006	20	10.1	53	17.4	10.6	51	5.6%	0.25 [-0.14, 0.64]	<b></b>
Thieme 2006	3.2	1.4	42	4.1	1.5	40	4.6%	-0.62 [-1.06 , -0.17]	
Thorn 2011	5	2.4	28	4.6	2.1	26	3.5%	0.17 [-0.36, 0.71]	
Thorn 2018	5.8	2.2	71	6	2	68	6.7%	-0.09 [-0.43, 0.24]	
Turner 2006	3.9	2.6	72	4.7	2.3	76	6.9%	-0.32 [-0.65 , -0.00]	
Vitiello 2013	4.1	3.7	221	4	2.7	120	9.9%	0.03 [-0.19 , 0.25]	+
Total (95% CI)			1285			1077	100.0%	-0.08 [-0.19 , 0.04]	•
Heterogeneity: Tau <sup>2</sup> = 0 Test for overall effect: 2 Test for subgroup diffe:	Z = 1.32 (P =	0.19)	15 (P = 0.0	04); I <sup>2</sup> = 42%	Ď				-2 -1 0 1 2 Favours CBT Favours active contr

### Analysis 1.4. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 4: Pain follow-up

## Analysis 1.5. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 5: Disability follow-up

		СВТ		Active tr	eatment c	ontrol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	48.8	9.1	56	52.8	9.2	53	6.8%	-0.43 [-0.81 , -0.05]	
Ersek 2008	11.6	5.7	114	11.9	5.6	103	9.1%	-0.05 [-0.32, 0.21]	
Greco 2004	-50.48	25.53	32	-50.22	23.86	33	5.1%	-0.01 [-0.50, 0.48]	
Kaapa 2006	18.9	12.8	53	18.5	12.4	54	6.8%	0.03 [-0.35, 0.41]	
Keefe 1990	1.69	1.16	30	2.63	1.5	35	4.9%	-0.69 [-1.19 , -0.18]	
Kraaimaat 1995	8.1	5.6	24	10.1	6.6	28	4.4%	-0.32 [-0.87, 0.23]	
Lera 2009	55.6	11.5	35	54.9	12.8	31	5.2%	0.06 [-0.43, 0.54]	
Litt 2009	1.9	1.5	52	1.4	1.1	29	5.5%	0.36 [-0.10, 0.82]	<b></b>
Lumley 2014	1.8	6	130	1.8	0.6	134	9.6%	0.00 [-0.24, 0.24]	_ <b>_</b> _
Lumley 2017	-39.1	9.9	75	-36.9	9.5	76	7.9%	-0.23 [-0.55, 0.09]	
Mangels 2009	22.3	15.1	232	20.6	13.5	131	10.3%	0.12 [-0.10, 0.33]	
Smeets 2006	11.8	5.8	53	10.9	5.7	51	6.7%	0.16 [-0.23, 0.54]	_ <b>_</b>
Thieme 2006	3.4	2	42	5.2	2.5	40	5.6%	-0.79 [-1.24 , -0.34]	
Thorn 2011	8.2	3.3	28	9.8	9.8	26	4.5%	-0.22 [-0.75, 0.32]	
Thorn 2018	5.6	2.7	71	6	2.4	68	7.6%	-0.16 [-0.49 , 0.18]	
Total (95% CI)			1027			892	100.0%	-0.12 [-0.26 , 0.02]	
Heterogeneity: Tau <sup>2</sup> = 0	0.04; Chi <sup>2</sup> = 2	9.85, df =	14 (P = 0.0)	008); I <sup>2</sup> = 53	%				•
Test for overall effect: 2	Z = 1.67 (P =	0.09)							-2 -1 0 1 2

Test for subgroup differences: Not applicable

Favours CBT

Favours active control

# Analysis 1.6. Comparison 1: Cognitive behavioural vs active control at the end of treatment, Outcome 6: Distress follow-up

		СВТ		Active tr	eatment c	ontrol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.9	2.5	56	8.2	2	53	5.9%	-0.13 [-0.51 , 0.24]	
Ersek 2008	11.2	3.1	114	10.8	2.7	103	8.3%	0.14 [-0.13, 0.40]	
Greco 2004	15.01	10.5	32	14.17	11.64	33	4.2%	0.07 [-0.41, 0.56]	<b>_</b>
Kaapa 2006	5.7	4.6	53	5.8	5.7	54	5.8%	-0.02 [-0.40, 0.36]	
Keefe 1990	2.51	1.33	30	2.92	1.94	35	4.2%	-0.24 [-0.73, 0.25]	_ <b>_</b>
Kraaimaat 1995	3.3	3.4	24	4	4.2	28	3.6%	-0.18 [-0.73 , 0.37]	
Litt 2009	10.7	7	52	11.7	9.2	49	5.6%	-0.12 [-0.51, 0.27]	
Lumley 2014	2	0.7	130	2.1	0.7	134	8.9%	-0.14 [-0.38, 0.10]	
Lumley 2017	17.3	11.9	75	18.5	12.1	76	7.0%	-0.10 [-0.42, 0.22]	
Mangels 2009	10.6	8.3	232	11.4	8.2	131	9.7%	-0.10 [-0.31, 0.12]	
Smeets 2006	7.6	6.4	53	7.2	6.2	51	5.7%	0.06 [-0.32, 0.45]	
Thieme 2006	2.6	1.2	42	4.2	1.4	40	4.4%	-1.22 [-1.69 , -0.74]	_ <b>_</b>
Thorn 2011	17.2	11.1	28	16.8	9.7	26	3.7%	0.04 [-0.50, 0.57]	
Thorn 2018	9.7	6.7	71	10.5	6.4	68	6.7%	-0.12 [-0.45, 0.21]	
Turner 2006	8.3	9.1	72	11.4	10.1	76	6.9%	-0.32 [-0.64, 0.00]	
Vitiello 2013	6.1	12.1	221	6.4	8.7	120	9.5%	-0.03 [-0.25 , 0.20]	
Total (95% CI)			1285			1077	100.0%	-0.13 [-0.25 , -0.01]	•
Heterogeneity: Tau <sup>2</sup> = 0	0.03; Chi <sup>2</sup> = 2	8.77, df =	15 (P = 0.0)	02); I <sup>2</sup> = 48%	Ď				· ·
Test for overall effect:	Z = 2.10 (P =	0.04)							-2 -1 0 1 2
Test for subgroup differ	rences: Not a	pplicable							Favours CBT Favours active control

## Comparison 2. Cognitive behavioural vs treatment as usual

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
2.1 Pain post-treatment	29	2572	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.33, -0.10]
2.2 Disability post-treatment	28	2524	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.45, -0.19]
2.3 Distress post-treatment	27	2559	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.44, -0.24]
2.4 Pain follow-up	15	1674	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.27, -0.04]
2.5 Disability follow-up	15	1581	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.37, -0.05]
2.6 Distress follow-up	16	1757	Std. Mean Difference (IV, Random, 95% CI)	-0.25 [-0.37, -0.13]

## Analysis 2.1. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 1: Pain post-treatment

		CBT usual treat						Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	36.9	8.3	56	38.7	7.5	53	4.0%	-0.23 [-0.60 , 0.15]	
Altmaier 1992	2.05	0.74	21	2	0.89	21	2.4%	0.06 [-0.55, 0.66]	
Basler 1997	4.08	2.11	36	4.18	1.37	40	3.4%	-0.06 [-0.51 , 0.39]	
Bliokas 2007	5.6	1.5	32	5.5	2	25	2.9%	0.06 [-0.47, 0.58]	
Carson 2006	14	12.7	60	14.6	9.4	35	3.7%	-0.05 [-0.47 , 0.37]	
Castel 2013	5.7	1.9	81	6.9	1.8	74	4.6%	-0.64 [-0.97 , -0.32]	
Castro 2012	5.7	1.7	48	5.3	1.1	45	3.7%	0.28 [-0.13, 0.68]	
herkin 2014	4.9	1.7	96	5.4	1.6	104	5.0%	-0.30 [-0.58 , -0.02]	-
evers 2002	14.93	5.32	30	15.35	4.55	29	2.9%	-0.08 [-0.59 , 0.43]	
errando 2012	2.92	2.03	30	5.24	2.61	29	2.7%	-0.98 [-1.52 , -0.44]	
arcia-Palacios 2015	22.6	6.3	30	20.7	8.3	29	2.9%	0.26 [-0.26 , 0.77]	<b></b>
lombiewski 2010	4.6	1.9	65	5.7	1.7	51	4.1%	-0.60 [-0.98 , -0.23]	
reco 2004	1.98	0.87	32	1.65	0.89	27	2.9%	0.37 [-0.15, 0.89]	
elminen 2015	36.7	20.4	50	39	19	43	3.7%	-0.12 [-0.52, 0.29]	_
eutink 2012	65.2	12.7	31	67.2	16	30	3.0%	-0.14 [-0.64 , 0.37]	_
nsen 2001	-29.9	11.75	49	-28.6	15.7	48	3.8%	-0.09 [-0.49 , 0.31]	
rlsson 2015	3.88	1.05	23	3.67	0.75	24	2.5%	0.23 [-0.35 , 0.80]	<b>_</b>
efe 1990	4.61	1.73	31	5.68	1.62	28	2.9%	-0.63 [-1.15 , -0.10]	
t 2009	1.5	1.4	32	1.2	1	22	2.7%	0.24 [-0.31, 0.78]	
crae 2019	27.2	14.6	76	29.8	14.5	37	3.9%	-0.18 [-0.57 , 0.22]	
shra 2000	42.5	15.11	24	42.53	23.56	25	2.6%	-0.00 [-0.56 , 0.56]	
cholas 2013	4.7	2.1	49	5.5	2.1	39	3.6%	-0.38 [-0.80 , 0.05]	
der 1988	3.19	0.89	31	3.26	0.66	38	3.2%	-0.09 [-0.56 , 0.38]	
neets 2006	37.8	24.3	55	53.4	22.6	49	3.9%	-0.66 [-1.05 , -0.26]	
omers 2012	4.5	2.1	101	4.8	2	41	4.2%	-0.14 [-0.51, 0.22]	-
horn 2018	5.4	2.3	83	6.2	1.8	78	4.7%	-0.38 [-0.70 , -0.07]	
arner 1988	15.91	11.63	24	22.14	12.35	21	2.4%	-0.51 [-1.11, 0.08]	
an Koulil 2010	15.9	3.6	61	17.9	3.9	81	4.4%	-0.53 [-0.87 , -0.19]	
illiams 1996	60	21.7	38	68.1	20.7	31	3.2%	-0.38 [-0.86 , 0.10]	
'otal (95% CI)			1375			1197	100.0%	-0.22 [-0.33 , -0.10]	•
Heterogeneity: Tau <sup>2</sup> = 0.	05; Chi <sup>2</sup> = 55	.45, df = 2	8 (P = 0.00)	02); I <sup>2</sup> = 50%	6				<b>v</b>
est for overall effect: Z	= 3.76 (P = 0)	.0002)							-2 -1 0 1 2
	ences: Not app	1 1. 1 .							Favours CBT Favours

## Analysis 2.2. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 2: Disability post-treatment

		CBT			usual treatment/waitlist			Std. Mean Difference	Std. Mean Difference
udy or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
da 2011	46.2	9.2	56	48.6	6.8	53	4.1%	-0.29 [-0.67 , 0.08]	-=
tmaier 1992	57.43	15.06	21	57.67	16.37	21	2.6%	-0.01 [-0.62, 0.59]	
sler 1997	1.63	0.87	36	1.84	0.62	40	3.5%	-0.28 [-0.73, 0.17]	-
iokas 2007	39.1	10.1	33	38.7	16	23	3.0%	0.03 [-0.50 , 0.56]	+
stel 2013	47.7	20.2	81	65.8	16.1	74	4.4%	-0.98 [-1.32 , -0.65]	+
tro 2012	-22.4	20.1	48	-13.5	19	45	3.8%	-0.45 [-0.86 , -0.04]	
rkin 2014	7.9	5.1	98	9.2	5	106	4.8%	-0.26 [-0.53, 0.02]	
s 2002	2.46	0.47	30	2.4	0.38	29	3.2%	0.14 [-0.37, 0.65]	
ndo 2012	0.98	1.09	30	0.99	1.21	29	3.2%	-0.01 [-0.52, 0.50]	
a-Palacios 2015	42.4	15.7	30	57	17.5	29	3.0%	-0.87 [-1.40 , -0.33]	
nbiewski 2010	3.9	2.2	65	4.4	2	51	4.1%	-0.23 [-0.60, 0.13]	-
2004	47.82	22.88	32	39.02	25.63	27	3.1%	0.36 [-0.16, 0.88]	L
nen 2015	35.8	21	54	38.2	20.9	47	4.0%	-0.11 [-0.50 , 0.28]	-
ık 2012	38	25.4	31	44.2	27.6	30	3.2%	-0.23 [-0.73, 0.27]	_
2001	-55.7	16.1	49	-58.4	19.7	48	3.9%	0.15 [-0.25, 0.55]	-
on 2015	2.8	0.63	23	2.85	0.67	24	2.8%	-0.08 [-0.65, 0.50]	-
1990	2.06	1.29	31	1.96	1.26	28	3.2%	0.08 [-0.43, 0.59]	
09	1	1	32	1.7	1.4	22	2.9%	-0.59 [-1.14 , -0.03]	-
2019	33	16.5	76	35.7	16.8	37	3.9%	-0.16 [-0.56, 0.23]	-
as 2013	9.7	4.9	49	12.8	5.5	39	3.7%	-0.59 [-1.02 , -0.16]	-
988	2.62	0.81	31	2.97	0.68	38	3.3%	-0.47 [-0.95, 0.01]	
2012	1.1	1.3	53	1.7	1.3	25	3.3%	-0.46 [-0.94, 0.02]	
\$ 2006	11.2	5.5	55	13.9	4.8	50	4.0%	-0.52 [-0.91, -0.13]	-
rs 2012	1.3	1	101	1.6	0.8	41	4.1%	-0.32 [-0.68, 0.05]	-
n 2018	5	2.7	83	6.1	2.5	78	4.5%	-0.42 [-0.73, -0.11]	+
er 1988	5.39	3.91	24	5.75	6.9	21	2.7%	-0.06 [-0.65 , 0.52]	-
Koulil 2010	17	4.2	61	20.2	3.8	87	4.3%	-0.80 [-1.14 , -0.46]	+
ams 1996	15.81	11.2	38	29.65	10.82	31	3.1%	-1.24 [-1.76 , -0.72]	
al (95% CI)			1351			1173	100.0%	-0.32 [-0.45 , -0.19]	•
progeneity: Tau <sup>2</sup> = 0.0	07; Chi <sup>2</sup> = 68	.46, df = 2	7 (P < 0.00)	001); I <sup>2</sup> = 61	%			- / •	*
or overall effect: Z									-4 -2 0 2
		plicable							Favours CBT Favours

## Analysis 2.3. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 3: Distress post-treatment

		СВТ		usual tro	eatment/w	aitlist		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.8	2.5	56	8.2	2.3	53	4.3%	-0.17 [-0.54 , 0.21]	-
Altmaier 1992	14.19	5.61	21	14	5.92	21	2.2%	0.03 [-0.57, 0.64]	<u> </u>
Bliokas 2007	12.9	10.3	31	19.8	12.5	25	2.7%	-0.60 [-1.14 , -0.06]	
Carson 2006	2.9	3.6	60	3.9	4.5	35	3.8%	-0.25 [-0.67, 0.17]	-
Castel 2013	14.3	9	81	21.7	8.4	74	5.0%	-0.84 [-1.17 , -0.52]	+
Castro 2012	-49.2	19.5	48	-44.2	21.2	45	3.9%	-0.24 [-0.65 , 0.16]	-
Cherkin 2014	3.2	2.8	96	5.3	4.3	104	5.8%	-0.57 [-0.86 , -0.29]	+
Evers 2002	9.98	4.62	30	12.85	7.87	29	2.8%	-0.44 [-0.96 , 0.08]	-
Ferrando 2012	0.44	0.54	30	0.63	0.93	29	2.9%	-0.25 [-0.76, 0.26]	-
Garcia-Palacios 2015	16.6	8.5	30	19.7	10	29	2.9%	-0.33 [-0.84 , 0.18]	
Glombiewski 2010	13.3	10.2	65	15.1	7.5	51	4.5%	-0.20 [-0.56 , 0.17]	-
Greco 2004	14.86	10.07	32	20.33	14.14	27	2.8%	-0.45 [-0.97, 0.07]	
Helminen 2015	5.5	4.5	54	6.1	6.3	47	4.1%	-0.11 [-0.50, 0.28]	4
Jensen 2001	-63.7	21.65	49	-64.75	18.55	48	4.0%	0.05 [-0.35, 0.45]	+
Karlsson 2015	2.9	0.7	23	2.9	0.6	24	2.4%	0.00 [-0.57, 0.57]	
Keefe 1990	2.59	1.65	31	3.42	1.8	28	2.8%	-0.48 [-0.99, 0.04]	
Litt 2009	10.9	10.7	32	11	10.8	22	2.6%	-0.01 [-0.55, 0.53]	
Macrae 2019	12.1	10.9	76	16.9	10.9	37	4.1%	-0.44 [-0.83 , -0.04]	-
Nicholas 2013	8.3	8.7	49	12.1	10.2	39	3.7%	-0.40 [-0.83 , 0.02]	-
Sharpe 2012	4.8	3.3	53	4.3	2.9	25	3.2%	0.16 [-0.32, 0.63]	-
Smeets 2006	8.3	5.4	55	9.6	7.9	49	4.2%	-0.19 [-0.58 , 0.19]	
Somers 2012	2.4	1.5	101	2.8	1.7	51	4.9%	-0.25 [-0.59, 0.08]	
Thorn 2018	9.1	5.8	83	11.4	6.6	78	5.3%	-0.37 [-0.68 , -0.06]	-
Turner 1988	18.2	14.1	24	23.3	21.8	21	2.3%	-0.28 [-0.87, 0.31]	
Van Koulil 2010	4.3	3.6	61	7.5	4.9	82	4.8%	-0.72 [-1.07 , -0.38]	+
Wang 2018	55.7	6.2	78	58.7	6.5	78		-0.47 [-0.79 , -0.15]	+
Williams 1996	9.5	7.8	38	17.3	7	21	2.5%	-1.02 [-1.59 , -0.46]	-
Total (95% CI)			1387			1172	100.0%	-0.34 [-0.44 , -0.24]	•
Heterogeneity: Tau <sup>2</sup> = 0.	.02; $Chi^2 = 40$	.54, df = 2	6 (P = 0.03)	3); I <sup>2</sup> = 36%					*
Test for overall effect: Z									-+ $-2$ 0 2 4
Test for subgroup differe									Favours CBT Favours usual treatmen

	CBT			usual treatment/waitlist				Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Alda 2011	40.7	10.9	56	44.3	8.6	53	6.8%	-0.36 [-0.74 , 0.02]		
Altmaier 1992	2.33	0.8	21	2	0.95	21	3.1%	0.37 [-0.24, 0.98]		
Castel 2013	6.7	1.6	81	7.1	1.8	74	8.9%	-0.23 [-0.55 , 0.08]	_ <b>_</b>	
Cherkin 2014	4.3	2	86	5	1.8	100	10.0%	-0.37 [-0.66 , -0.08]		
Evers 2002	14.99	5.12	30	15.79	4.98	29	4.2%	-0.16 [-0.67 , 0.35]		
Greco 2004	2.05	0.94	32	1.69	1.15	27	4.1%	0.34 [-0.17, 0.86]		
Haldorsen 1998	48.2	27.4	93	52.1	28.9	94	10.2%	-0.14 [-0.42, 0.15]	_ <b>_</b>	
Helminen 2015	36.6	24.9	51	38	25	44	6.2%	-0.06 [-0.46 , 0.35]		
Jensen 2001	-33.35	16.15	49	-32.85	20.05	48	6.3%	-0.03 [-0.43 , 0.37]		
Keefe 1990	5.22	2.08	30	5.64	1.79	28	4.1%	-0.21 [-0.73 , 0.30]	<b>-</b> _	
Macrae 2019	26.4	15.7	76	23.3	16	37	6.4%	0.19 [-0.20, 0.59]	<b>_</b>	
Martin 2012	7.2	2.2	54	8.2	1.6	56	6.8%	-0.52 [-0.90 , -0.14]		
Somers 2012	4.2	2	92	4.6	2.1	37	6.7%	-0.20 [-0.58 , 0.19]		
Thorn 2018	5.8	2.2	71	5.9	1.8	71	8.4%	-0.05 [-0.38 , 0.28]		
Van Koulil 2010	16.7	6.4	55	18.2	3.5	78	7.8%	-0.30 [-0.65 , 0.04]		
Total (95% CI)			877			797	100.0%	-0.16 [-0.27 , -0.04]		
Heterogeneity: Tau <sup>2</sup> = 0	0.01; Chi <sup>2</sup> = 1	8.17, df =	14 (P = 0.2)	20); I <sup>2</sup> = 23%	6				•	
Test for overall effect: 2	Z = 2.69 (P =	0.007)							-1 -0.5 0 0.5 1	
Test for subgroup differ	rences: Not ap	plicable							Favours CBT Favours usual treatment	

## Analysis 2.4. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 4: Pain follow-up

## Analysis 2.5. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 5: Disability follow-up

		СВТ		usual tro	eatment/w	aitlist		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	48.8	9.1	56	53.3	7.5	53	7.1%	-0.53 [-0.92 , -0.15]	_
Altmaier 1992	52.19	19.58	21	50.71	25.95	21	4.4%	0.06 [-0.54, 0.67]	_ <b>_</b>
Castel 2013	58.8	20.5	81	69.6	17.2	74	8.0%	-0.57 [-0.89 , -0.24]	
Cherkin 2014	6.4	5.3	92	7.6	5.4	106	8.7%	-0.22 [-0.50, 0.06]	
Evers 2002	2.42	0.47	30	2.37	0.4	29	5.3%	0.11 [-0.40, 0.62]	_ <b>_</b>
Greco 2004	49.52	25.53	32	43.05	27.3	27	5.3%	0.24 [-0.27, 0.76]	
Helminen 2015	37.5	25.4	52	34.6	24.3	45	6.8%	0.12 [-0.28, 0.51]	_ <b>_</b>
Jensen 2001	-58.2	18.65	49	-59.05	24.3	48	6.8%	0.04 [-0.36, 0.44]	_ <b>_</b>
Keefe 1990	1.69	1.16	30	1.96	1.43	28	5.3%	-0.21 [-0.72, 0.31]	
Macrae 2019	32.1	17.6	76	34.9	18.1	37	6.9%	-0.16 [-0.55 , 0.24]	
Martin 2012	70.3	17	54	76.8	14.2	56	7.1%	-0.41 [-0.79 , -0.03]	
Sharpe 2012	1	1.1	53	1	1	25	5.8%	0.00 [-0.48, 0.48]	_
Somers 2012	1.3	1	92	1.3	0.9	37	7.1%	0.00 [-0.38 , 0.38]	
Thorn 2018	5.6	2.7	71	6.3	2.2	71	7.9%	-0.28 [-0.61 , 0.05]	
Van Koulil 2010	17.3	4.3	56	21.1	4.4	79	7.4%	-0.87 [-1.22 , -0.51]	_ <b>-</b> _
Total (95% CI)		-0.21 [-0.37 , -0.05]							
Heterogeneity: Tau <sup>2</sup> = 0	0.05; Chi <sup>2</sup> = 3		•						
Test for overall effect: 2	Z = 2.59 (P =	0.010)							-2 $-1$ $0$ $1$ $2$
Test for subgroup differ	ences: Not ap	plicable							Favours CBT Favours usual treatment

#### Analysis 2.6. Comparison 2: Cognitive behavioural vs treatment as usual, Outcome 6: Distress follow-up

		СВТ		usual treatment/waitlist				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.9	2.5	56	8.6	2.5	53	6.6%	-0.28 [-0.66 , 0.10]	
Altmaier 1992	16.24	4.22	21	15	6.15	21	3.3%	0.23 [-0.38 , 0.84]	_ <b>_</b>
Castel 2013	17.1	9.9	81	22.8	9.2	74	8.0%	-0.59 [-0.91 , -0.27]	-
Cherkin 2014	3.5	3.2	86	4.6	3.9	100	8.9%	-0.30 [-0.59 , -0.01]	-
Evers 2002	9.51	5.35	30	13.07	7.51	29	4.2%	-0.54 [-1.06 , -0.02]	
Greco 2004	15.01	10.5	32	16.99	12.94	27	4.3%	-0.17 [-0.68 , 0.35]	
Haldorsen 1998	35.4	10.3	93	36.9	9.9	94	9.0%	-0.15 [-0.43 , 0.14]	-
Helminen 2015	6	5.2	53	5.4	6.4	45	6.2%	0.10 [-0.29 , 0.50]	-
ensen 2001	-67.5	20.9	49	-61.65	26.3	48	6.1%	-0.24 [-0.64 , 0.15]	
Keefe 1990	2.51	1.33	30	3.06	1.52	28	4.2%	-0.38 [-0.90, 0.14]	
Macrae 2019	11.4	11.6	76	15	11.7	37	6.2%	-0.31 [-0.70 , 0.09]	
Martin 2012	9.8	4.1	54	10.3	4.2	56	6.7%	-0.12 [-0.49, 0.25]	-
Sharpe 2012	4.4	3.8	53	4	2.8	25	4.8%	0.11 [-0.36, 0.59]	
omers 2012	2.4	1.5	92	2.5	2.5	37	6.5%	-0.05 [-0.44 , 0.33]	
Thorn 2018	9.7	6.7	71	11.6	7.1	71	7.8%	-0.27 [-0.60, 0.06]	
Van Koulil 2010	4.1	3	57	7.2	4.8	78	7.2%	-0.74 [-1.10 , -0.39]	+
Total (95% CI)			934			823	100.0%	-0.25 [-0.37 , -0.13]	•
Heterogeneity: Tau <sup>2</sup> = 0	0.02; Chi <sup>2</sup> = 2	3.26, df =	15 (P = 0.0)	08); I <sup>2</sup> = 369	6				Ť
Test for overall effect: 2	Z = 4.08 (P <	0.0001)							
Test for subgroup differ	ences: Not a	pplicable							Favours CBT Favours usual treats

## Comparison 3. Behavioural vs active control

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
3.1 Pain post-treatment	2	144	Std. Mean Difference (IV, Random, 95% CI)	-0.67 [-2.54, 1.20]
3.2 Disability post-treatment	3	215	Std. Mean Difference (IV, Random, 95% CI)	-0.65 [-1.85, 0.54]
3.3 Distress post-treatment	3	215	Std. Mean Difference (IV, Random, 95% CI)	-0.73 [-1.47, 0.01]

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
3.4 Pain follow-up	2	144	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-1.02, 0.30]
3.5 Disability follow-up	3	212	Std. Mean Difference (IV, Random, 95% CI)	-1.09 [-2.03, -0.15]
3.6 Distress follow-up	3	212	Std. Mean Difference (IV, Random, 95% CI)	-0.90 [-1.47, -0.33]

## Analysis 3.1. Comparison 3: Behavioural vs active control, Outcome 1: Pain post-treatment

	Behavio	ural treat	tment	Act	ive contro	bl		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Thieme 2003	3.82	0.96	40	5.47	1.06	21	49.3%	-1.64 [-2.24 , -1.03]	
Thieme 2006	4.1	1.1	43	3.8	1.1	40	50.7%	0.27 [-0.16 , 0.70]	-
Total (95% CI)			83			61	100.0%	-0.67 [-2.54 , 1.20]	
Heterogeneity: Tau <sup>2</sup> = 1	.75; Chi <sup>2</sup> = 25	5.12, df =	1 (P < 0.00)	0001); I <sup>2</sup> = 9	96%				
Test for overall effect: 2	Z = 0.70 (P =	0.48)							-2 -1 0 1 2
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours active control

## Analysis 3.2. Comparison 3: Behavioural vs active control, Outcome 2: Disability post-treatment

	Behavio	ural trea	tment	Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Nicassio 1997	0.4	0.08	36	0.42	0.08	35	33.8%	-0.25 [-0.71 , 0.22]	
Thieme 2003	3.29	1.02	40	5.28	0.86	21	32.2%	-2.03 [-2.67 , -1.38]	_ <b>_</b>
Thieme 2006	4.5	1.9	43	4	2.1	40	34.0%	0.25 [-0.18 , 0.68]	-
Total (95% CI)			119			96	100.0%	-0.65 [-1.85 , 0.54]	
Heterogeneity: Tau <sup>2</sup> = 1	$1.04; Chi^2 = 3$	3.41, df =	2 (P < 0.00)	0001); I <sup>2</sup> = 9	94%				
Test for overall effect: 2	Z = 1.07 (P =	0.28)							-4 -2 0 2 4
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours active control

## Analysis 3.3. Comparison 3: Behavioural vs active control, Outcome 3: Distress post-treatment

	Behavio	oural treat	tment	Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Thieme 2003	2.54	1.03	40	4.46	1.48	21	31.3%	-1.58 [-2.18 , -0.98]	_ <b>_</b>
Nicassio 1997	15.47	12.13	36	20.69	9.83	35	34.0%	-0.47 [-0.94 , 0.00]	
Thieme 2006	3.3	1.3	43	3.6	1.3	40	34.8%	-0.23 [-0.66 , 0.20]	
Total (95% CI)			119			96	100.0%	-0.73 [-1.47 , 0.01]	
Heterogeneity: Tau <sup>2</sup> = 0	0.36; Chi <sup>2</sup> = 1	3.26, df =	2 (P = 0.0)	01); I <sup>2</sup> = 85%	6				•
Test for overall effect: 2	Z = 1.94 (P =	0.05)							-2 -1 0 1 2
Test for subgroup differ	rences: Not ap	oplicable							Favours BT Favours active control



#### Analysis 3.4. Comparison 3: Behavioural vs active control, Outcome 4: Pain follow-up

	Behavio	Behavioural treatment			Active control			Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Thieme 2003	3.66	182	40	4.85	0.86	21	47.7%	-0.01 [-0.54 , 0.52]		
Thieme 2006	3.1	1.4	43	4.1	1.5	40	52.3%	-0.68 [-1.13 , -0.24]		
Total (95% CI)			83			61	100.0%	-0.36 [-1.02 , 0.30]		
Heterogeneity: Tau <sup>2</sup> = 0	.17; Chi <sup>2</sup> = 3.	69, df = 1	(P = 0.05)	; I <sup>2</sup> = 73%					•	
Test for overall effect: 2	Z = 1.07 (P =	0.28)							-2 -1 0 1 2	
Test for subgroup differ	ences: Not ap	plicable							Favours BT Favours active control	

## Analysis 3.5. Comparison 3: Behavioural vs active control, Outcome 5: Disability follow-up

	Behavio	ural trea	tment	Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Nicassio 1997	0.4	0.11	36	0.42	0.09	35	34.1%	-0.20 [-0.66 , 0.27]	-
Thieme 2003	2.96	1.18	29	4.83	0.72	29	31.9%	-1.89 [-2.51 , -1.26]	_ <b>_</b>
Thieme 2006	2.6	1.6	43	5.2	2.5	40	34.0%	-1.24 [-1.71 , -0.77]	+
Total (95% CI)			108			104	100.0%	-1.09 [-2.03 , -0.15]	•
Heterogeneity: Tau <sup>2</sup> = 0	).62; Chi <sup>2</sup> = 20	0.05, df =	2 (P < 0.00)	001); I <sup>2</sup> = 90	)%				•
Test for overall effect: 2	Z = 2.27 (P =	0.02)							-4 -2 0 2 4
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours active control

## Analysis 3.6. Comparison 3: Behavioural vs active control, Outcome 6: Distress follow-up

	Behavio	ural treat	ment	Act	ive contro	bl		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Nicassio 1997	13.7	10.06	36	17.72	11.32	35	34.4%	-0.37 [-0.84 , 0.10]	<b>_</b> _
Thieme 2003	2.38	1.29	29	4.47	1.65	29	30.7%	-1.39 [-1.97 , -0.81]	_ <b>_</b>
Thieme 2006	2.9	1.2	43	4.2	1.4	40	34.9%	-0.99 [-1.45 , -0.53]	
Total (95% CI)			108			104	100.0%	-0.90 [-1.47 , -0.33]	
Heterogeneity: Tau <sup>2</sup> = 0	0.19; Chi <sup>2</sup> = 7.	73, df = 2	(P = 0.02)	; <b>I</b> <sup>2</sup> = 74%					•
Test for overall effect: 2	Z = 3.12 (P =	0.002)							-2 $-1$ 0 1 2
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours active control

#### Comparison 4. Behavioural vs treatment as usual

No. of studies	No. of partici- pants	Statistical method	Effect size
3	308	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.33, 0.17]
4	379	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.24, 0.19]
2	153	Std. Mean Difference (IV, Random, 95% CI)	0.22 [-0.10, 0.54]
1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
3	329	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.18, 0.46]
2	153	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.06, 0.57]
	studies           3           4           2           1           3	studiesparticipants3308437921531329	studiesparticipants3308Std. Mean Difference (IV, Random, 95% CI)4379Std. Mean Difference (IV, Random, 95% CI)2153Std. Mean Difference (IV, Random, 95% CI)1Std. Mean Difference (IV, Random, 95% CI)3329Std. Mean Difference (IV, Random, 95% CI)

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	Behavi	oural the	rapy	usual tre	atment/wa	ait list		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Geraets 2005	1.7	2.2	81	1.5	2.2	77	48.3%	0.09 [-0.22 , 0.40]		
Jensen 2001	-33.55	16.7	54	-28.6	15.7	48	33.9%	-0.30 [-0.69, 0.09]	_ <b>_</b>	
Mishra 2000	40	22.25	23	42.53	23.56	25	17.8%	-0.11 [-0.68 , 0.46]		
Total (95% CI)			158			150	100.0%	-0.08 [-0.33 , 0.17]		
Heterogeneity: Tau <sup>2</sup> = 0	$0.01; Chi^2 = 2$	.39, df = 2	(P = 0.30)	; I <sup>2</sup> = 16%					1	
Test for overall effect:	Z = 0.61 (P =	0.54)							-2 -1 0 1 2	
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours contro	

#### Analysis 4.1. Comparison 4: Behavioural vs treatment as usual, Outcome 1: Pain post-treatment

#### Analysis 4.2. Comparison 4: Behavioural vs treatment as usual, Outcome 2: Disability post-treatment

	Behavi	oural the	rapy	usual tre	atment/wa	ait list		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Geraets 2005	17	26	87	15.3	21.6	89	44.7%	0.07 [-0.22 , 0.37]		
Jensen 2001	-61.75	14.8	54	-58.4	19.7	48	27.4%	-0.19 [-0.58 , 0.20]		
Sharpe 2012	2.3	2.7	25	1.7	1.3	26	14.3%	0.28 [-0.27, 0.83]		
Turner 1988	3.96	4.7	29	5.74	6.9	21	13.7%	-0.31 [-0.87 , 0.26]		
Гоtal (95% CI)			195			184	100.0%	-0.02 [-0.24 , 0.19]	•	
Heterogeneity: Tau <sup>2</sup> = 0	0.00; Chi <sup>2</sup> = 3.	24, $df = 3$	(P = 0.36)	; $I^2 = 7\%$					T	
Test for overall effect: 2	Z = 0.21 (P = 0.21)	0.83)							-1 -0.5 0 0.5	
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours contr	

#### Analysis 4.3. Comparison 4: Behavioural vs treatment as usual, Outcome 3: Distress post-treatment

	Behavi	oural the	rapy	usual tre	atment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Jensen 2001	-61.45	18.65	54	-64.75	18.55	48	66.8%	0.18 [-0.21 , 0.57]	
Sharpe 2012	5.3	3.3	25	4.3	2.9	26	33.2%	0.32 [-0.24 , 0.87]	
Total (95% CI)			79			74	100.0%	0.22 [-0.10 , 0.54]	
Heterogeneity: Tau <sup>2</sup> = 0	$0.00; Chi^2 = 0$	.17, df = 1	(P = 0.68)	; $I^2 = 0\%$					•
Test for overall effect: 2	Z = 1.37 (P =	0.17)							-2 -1 0 1 2
Test for subgroup differ	ences: Not ap	plicable							Favours BT Favours control

## Analysis 4.4. Comparison 4: Behavioural vs treatment as usual, Outcome 4: Pain follow-up

	Behavi	ioural the	rapy	usual tre	eatment/w	ait list	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Random, 95% CI	IV, Random, 95% CI
Jensen 2001	-33.55	19.65	54	-32.85	20.05	48	-0.04 [-0.42 , 0.35]	
								-2 -1 0 1 2 Favours BT Favours control

## Analysis 4.5. Comparison 4: Behavioural vs treatment as usual, Outcome 5: Disability follow-up

	Behavi	oural the	rapy	usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Geraets 2005	20.4	31.4	89	22.5	26.2	87	43.8%	-0.07 [-0.37 , 0.22]		
Jensen 2001	-55.5	20.75	54	-59.05	24.3	48	34.2%	0.16 [-0.23, 0.55]		
Sharpe 2012	1.7	1.5	25	1	1	26	22.1%	0.54 [-0.02 , 1.10]		
Total (95% CI)			168			161	100.0%	0.14 [-0.18 , 0.46]		
Heterogeneity: Tau <sup>2</sup> = 0	0.04; Chi <sup>2</sup> = 3.	78, $df = 2$	(P = 0.15)	; $I^2 = 47\%$					•	
Test for overall effect: 2	Z = 0.88 (P =	0.38)							-2 -1 0 1 2	
Test for subgroup differ	ences: Not ap	plicable							Favours BT Favours control	

#### Analysis 4.6. Comparison 4: Behavioural vs treatment as usual, Outcome 6: Distress follow-up

	Behavi	oural the	rapy	usual tre	atment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Jensen 2001	-55.95	23.4	54	-61.65	26.3	48	66.7%	0.23 [-0.16 , 0.62]	
Sharpe 2012	5.2	4.6	25	4	2.8	26	33.3%	0.31 [-0.24 , 0.86]	
Total (95% CI)			79			74	100.0%	0.26 [-0.06 , 0.57]	
Heterogeneity: Tau <sup>2</sup> = 0	$0.00; Chi^2 = 0$	.06, df = 1	(P = 0.81)	; $I^2 = 0\%$					-
Test for overall effect:	-1 -0.5 0 0.5 1								
Test for subgroup differ	rences: Not ap	plicable							Favours BT Favours control

### Comparison 5. Acceptance commitment therapy vs active control

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
5.1 Pain post-treatment	5	385	Std. Mean Difference (IV, Random, 95% CI)	-0.54 [-1.20, 0.11]
5.2 Disability post-treatment	4	260	Std. Mean Difference (IV, Random, 95% CI)	-1.51 [-3.05, 0.03]
5.3 Distress post-treatment	5	385	Std. Mean Difference (IV, Random, 95% CI)	-0.61 [-1.30, 0.07]
5.4 Pain follow-up	3	265	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-1.03, 0.27]
5.5 Disability follow-up	2	156	Std. Mean Difference (IV, Random, 95% CI)	-2.56 [-4.22, -0.89]
5.6 Distress follow-up	3	265	Std. Mean Difference (IV, Random, 95% CI)	-0.58 [-1.24, 0.07]

#### Analysis 5.1. Comparison 5: Acceptance commitment therapy vs active control, Outcome 1: Pain post-treatment

		ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alonso-Fernandez 2016	5.38	3.66	27	5	2.52	26	19.7%	0.12 [-0.42 , 0.66]	
Luciano 2014	48.1	10.5	51	57.2	11.2	52	20.9%	-0.83 [-1.24 , -0.43]	+
Pincus 2015	14.1	8.3	23	15.8	9.9	26	19.5%	-0.18 [-0.74, 0.38]	-
Thorsell 2011	7.2	0.4	28	8	0.4	27	18.5%	-1.97 [-2.62 , -1.32]	
Wiklund 2018	5.6	2	64	5.5	2.1	61	21.3%	0.05 [-0.30 , 0.40]	+
Total (95% CI)			193			192	100.0%	-0.54 [-1.20 , 0.11]	
Heterogeneity: Tau <sup>2</sup> = 0.49;	Chi <sup>2</sup> = 37.10	, df = 4 (P	< 0.00001	); $I^2 = 89\%$					•
Test for overall effect: $Z = 1$	1.62 (P = 0.10)	)							-4 -2 0 2 4
Test for subgroup difference	es: Not applic	able							Favours ACT Favours active control

## Analysis 5.2. Comparison 5: Acceptance commitment therapy vs active control, Outcome 2: Disability post-treatment

		ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alonso-Fernandez 2016	4.7	3.24	27	4.77	3.85	26	25.4%	-0.02 [-0.56 , 0.52]	+
Luciano 2014	48.7	6.9	51	63.4	9.1	52	25.6%	-1.80 [-2.27 , -1.34]	+
Pincus 2015	9	6.3	23	8.9	6.7	26	25.4%	0.02 [-0.55, 0.58]	
Thorsell 2011	4.4	0.4	28	6.2	0.4	27	23.6%	-4.44 [-5.45 , -3.43]	
Total (95% CI)			129			131	100.0%	-1.51 [-3.05 , 0.03]	
Heterogeneity: Tau <sup>2</sup> = 2.36;	Chi <sup>2</sup> = 81.40	, df = 3 (P	< 0.00001	); I <sup>2</sup> = 96%					-
Test for overall effect: $Z = $	1.92 (P = 0.05)	i)							-4 -2 0 2 4
Test for subgroup difference	es: Not applic	able							Favours ACT Favours active control

### Analysis 5.3. Comparison 5: Acceptance commitment therapy vs active control, Outcome 3: Distress post-treatment

		ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alonso-Fernandez 2016	10.81	6.39	27	12	6.87	26	19.8%	-0.18 [-0.72 , 0.36]	
Luciano 2014	5.4	1.4	51	7.4	2.7	52	20.9%	-0.92 [-1.33 , -0.51]	-
Pincus 2015	5.2	3.4	23	5.4	3.4	26	19.6%	-0.06 [-0.62, 0.50]	-
Thorsell 2011	6.6	0.7	28	8.2	0.8	27	18.6%	-2.10 [-2.77 , -1.43]	
Wiklund 2018	5.9	3.8	64	5.6	3.7	61	21.3%	0.08 [-0.27 , 0.43]	+
Total (95% CI)			193			192	100.0%	-0.61 [-1.30 , 0.07]	
Heterogeneity: Tau <sup>2</sup> = 0.54;	Chi <sup>2</sup> = 40.24	, df = 4 (P	< 0.00001	); I <sup>2</sup> = 90%					▼
Test for overall effect: $Z = 1$	1.75 (P = 0.08)	)							-4 -2 0 2 4
Test for subgroup difference	Favours ACT Favours active control								

#### Analysis 5.4. Comparison 5: Acceptance commitment therapy vs active control, Outcome 4: Pain follow-up

		ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Luciano 2014	49.6	11	51	56.3	11.2	52	34.5%	-0.60 [-0.99 , -0.20]	+
Thorsell 2011	7.6	0.3	27	7.9	0.4	26	30.5%	-0.84 [-1.40 , -0.27]	
Wiklund 2018	5.4	2	55	4.9	2.3	54	34.9%	0.23 [-0.15 , 0.61]	+
Total (95% CI)			133			132	100.0%	-0.38 [-1.03 , 0.27]	•
Heterogeneity: Tau <sup>2</sup> =	0.28; Chi <sup>2</sup> = 1	3.32, df =	2 (P = 0.00)	01); I <sup>2</sup> = 85%	6				•
Test for overall effect:	Z = 1.15 (P =		-4 -2 0 2 4						
Test for subgroup diffe	erences: Not aj	pplicable							Favours ACT Favours active control

## Analysis 5.5. Comparison 5: Acceptance commitment therapy vs active control, Outcome 5: Disability follow-up

	ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Di	fference
Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random,	95% CI
49.5	8.8	51	65.1	8.9	52	52.5%	-1.75 [-2.21 , -1.29]		
4.6	0.4	27	6	0.4	26	47.5%	-3.45 [-4.32 , -2.58]	• •	
		78			78	100.0%	-2.56 [-4.22 , -0.89]		
.32; Chi <sup>2</sup> = 1	1.50, df =	1 (P = 0.00)	007); I <sup>2</sup> = 91	%				•	
L = 3.01 (P =	0.003)							-4 -2 0	2 4
ences: Not ap	plicable							Favours ACT	Favours active control
	$49.5 \\ 4.6 \\ 32; Chi2 = 1 \\ 2 = 3.01 (P = 1)$	Mean         SD           49.5         8.8           4.6         0.4	Mean         SD         Total           49.5         8.8         51           4.6         0.4         27           78           .32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.003)	Mean         SD         Total         Mean           49.5         8.8         51         65.1           4.6         0.4         27         6           78         78           32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); I <sup>2</sup> = 91         12         12 $= 3.01$ (P = 0.003)         12         12         12	Mean         SD         Total         Mean         SD           49.5         8.8         51         65.1         8.9           4.6         0.4         27         6         0.4           78           32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); l <sup>2</sup> = 91%           = 3.01 (P = 0.003)	Mean         SD         Total         Mean         SD         Total           49.5         8.8         51         65.1         8.9         52           4.6         0.4         27         6         0.4         26           78         78           32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); I <sup>2</sup> = 91%         50.0007         50.0007         50.0007	Mean         SD         Total         Mean         SD         Total         Weight           49.5         8.8         51         65.1         8.9         52         52.5%           4.6         0.4         27         6         0.4         26         47.5%           78         78         100.0%           .32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); I <sup>2</sup> = 91%         5	Mean         SD         Total         Mean         SD         Total         Weight         IV, Random, 95% CI           49.5         8.8         51         65.1         8.9         52         52.5% $-1.75$ [-2.21, $-1.29$ ]           4.6         0.4         27         6         0.4         26         47.5% $-3.45$ [-4.32, $-2.58$ ]           78         78         100.0%         -2.56 [-4.22, -0.89]           32; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); I <sup>2</sup> = 91% $= 3.01$ (P = 0.003)	Mean         SD         Total         Mean         SD         Total         Weight         IV, Random, 95% CI         IV, Random, 9 $49.5$ $8.8$ $51$ $65.1$ $8.9$ $52$ $52.5\%$ $-1.75$ $[-2.21, -1.29]$ $4.6$ $0.4$ $27$ $6$ $0.4$ $26$ $47.5\%$ $-3.45$ $[-4.32, -2.58]$ 78         78         100.0% $-2.56$ $[-4.22, -0.89]$ $-4$ $-2$ $0$ $32$ ; Chi <sup>2</sup> = 11.50, df = 1 (P = 0.0007); l <sup>2</sup> = 91% $-4$ $-2$ $0$ $-4$ $-2$ $0$

### Analysis 5.6. Comparison 5: Acceptance commitment therapy vs active control, Outcome 6: Distress follow-up

		ACT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Luciano 2014	5.8	1.6	51	7.5	2.8	52	34.6%	-0.74 [-1.14 , -0.34]	•
Thorsell 2011	7.3	0.8	27	8.2	0.8	26	30.2%	-1.11 [-1.69 , -0.53]	-
Wiklund 2018	5.5	3.8	55	5.4	3.7	54	35.1%	0.03 [-0.35 , 0.40]	+
Total (95% CI)			133			132	100.0%	-0.58 [-1.24 , 0.07]	
Heterogeneity: Tau <sup>2</sup> = 0	).28; Chi <sup>2</sup> = 1	3.07, df =	2 (P = 0.00)	01); I <sup>2</sup> = 859	%				•
Test for overall effect: 2	Z = 1.74 (P =	0.08)							-4 -2 0 2 4
Test for subgroup differ	ences: Not ap	plicable							Favours ACT Favours active control

## Comparison 6. Acceptance commitment therapy vs treatment as usual

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
6.1 Pain post-treatment	2	162	Std. Mean Difference (IV, Random, 95% CI)	-0.83 [-1.57, -0.09]
6.2 Disability post-treatment	2	162	Std. Mean Difference (IV, Random, 95% CI)	-1.39 [-3.20, 0.41]
6.3 Distress post-treatment	2	162	Std. Mean Difference (IV, Random, 95% CI)	-1.16 [-2.51, 0.20]
6.4 Pain follow-up	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
6.5 Disability follow-up	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
6.6 Distress follow-up	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected

## Analysis 6.1. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 1: Pain post-treatment

		ACT		usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Luciano 2014	48.1	10.5	51	64.3	15.8	53	52.2%	-1.19 [-1.61 , -0.78]	-
McCracken 2013	6.5	1.9	31	7.3	1.7	27	47.8%	-0.44 [-0.96 , 0.09]	
Total (95% CI)			82			80	100.0%	-0.83 [-1.57 , -0.09]	
Heterogeneity: Tau <sup>2</sup> = 0	0.23; Chi <sup>2</sup> = 4	.93, df = 1	(P = 0.03)	; I <sup>2</sup> = 80%					•
Test for overall effect: 2	Z = 2.20 (P =	0.03)							-4 -2 0 2 4
Test for subgroup differ	rences: Not ap	oplicable							Favours ACT Favours control

## Analysis 6.2. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 2: Disability post-treatment

		ACT			atment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Luciano 2014	48.7	6.9	51	67.7	9.2	53	50.1%	-2.31 [-2.81 , -1.81]	+
McCracken 2013	10	4.9	31	12.6	6	27	49.9%	-0.47 [-1.00 , 0.05]	
Total (95% CI)			82			80	100.0%	-1.39 [-3.20 , 0.41]	
Heterogeneity: Tau <sup>2</sup> = 1	.63; Chi <sup>2</sup> = 2	4.83, df =	1 (P < 0.00)	0001); I <sup>2</sup> = 9	6%				
Test for overall effect: Z	Z = 1.51 (P =	0.13)							-4 -2 0 2 4
Test for subgroup different	ences: Not aj	oplicable							Favours ACT Favours control

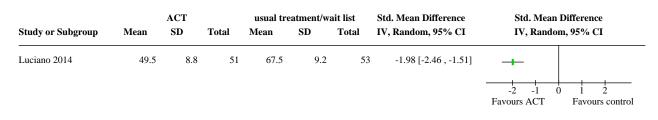
## Analysis 6.3. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 3: Distress post-treatment

		ACT			atment/w	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Luciano 2014	5.4	1.4	51	9.3	2.6	53	50.4%	-1.84 [-2.31 , -1.38]	
McCracken 2013	9.5	6.8	31	13	8.3	27	49.6%	-0.46 [-0.98 , 0.06]	
Total (95% CI)			82			80	100.0%	-1.16 [-2.51 , 0.20]	
Heterogeneity: Tau <sup>2</sup> = 0	).90; Chi <sup>2</sup> = 1	5.16, df =	1 (P < 0.00)	001); I <sup>2</sup> = 93	%				<u> </u>
Test for overall effect: 2	Z = 1.67 (P =	0.09)							-2 -1 0 1 2
Test for subgroup differ	rences: Not aj	pplicable							Favours ACT Favours control

#### Analysis 6.4. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 4: Pain follow-up

	ACT			usual tre	atment/wa	ait list	Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Random, 95% CI	IV, Random, 95% CI		
Luciano 2014	49.6	11	51	64.4	15.3	53	-1.10 [-1.51 , -0.69]	-+		
								-2 -1 ( Favours ACT	) 1 2 Favours control	

## Analysis 6.5. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 5: Disability follow-up



### Analysis 6.6. Comparison 6: Acceptance commitment therapy vs treatment as usual, Outcome 6: Distress follow-up

Study or Subgroup	ACT Mean SD Total			usual tre Mean	atment/wa SD	ait list Total	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI			
Luciano 2014	5.8	1.6	51	9.3	3	53	-1.44 [-1.87 , -1.00]	+			
								-4 -2 Favours ACT	D 2 4 Favours control		

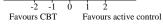
### Comparison 7. Sensitivity analysis - CBT vs active control

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
7.1 Pain post-treatment	27	3735	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.56, -0.10]
7.2 Disability post-treatment	23	3043	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.64, -0.17]
7.3 Distress post-treatment	26	3477	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.28, -0.02]
7.4 Pain follow-up	20	2862	Std. Mean Difference (IV, Random, 95% CI)	-0.46 [-0.79, -0.13]
7.5 Disability follow-up	19	2419	Std. Mean Difference (IV, Random, 95% CI)	-0.63 [-1.02, -0.24]
7.6 Distress follow-up	18	2542	Std. Mean Difference (IV, Random, 95% CI)	-0.26 [-0.47, -0.06]

## Analysis 7.1. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 1: Pain post-treatment

		CBT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Alda 2011	36.9	8.3	56	37.1	10.5	53	3.7%	-0.02 [-0.40 , 0.35]		
Carson 2006	14	12.7	60	15	10.4	33	3.6%	-0.08 [-0.51, 0.34]	_	
Ersek 2008	4.9	1.9	123	5	2.1	101	3.9%	-0.05 [-0.31, 0.21]	-	
Greco 2004	1.98	0.87	32	1.97	0.91	33	3.5%	0.01 [-0.48, 0.50]		
Kaapa 2006	3.3	2.5	59	3.4	2.4	61	3.8%	-0.04 [-0.40, 0.32]	-	
Keefe 1990	4.61	1.73	31	5.67	1.65	35	3.5%	-0.62 [-1.12 , -0.13]		
Keefe 1996	4.21	1.48	28	5.22	2.06	27	3.4%	-0.56 [-1.10 , -0.02]		
Kraaimaat 1995	14.8	4.3	24	15.4	4.6	28	3.4%	-0.13 [-0.68, 0.41]		
Litt 2009	2.7	1.4	52	2.7	1.3	49	3.7%	0.00 [-0.39 , 0.39]	+	
Lumley 2014	2.7	0.7	130	2.7	1.1	134	4.0%	0.00 [-0.24, 0.24]	+	
Lumley 2017	4.7	1.7	75	5.2	1.7	76	3.8%	-0.29 [-0.61 , 0.03]		
Mangels 2009	15.9	5.3	232	16.4	5.8	131	4.0%	-0.09 [-0.31, 0.12]	-	
Monticone 2013	2.7	1	45	5	1.3	45	3.4%	-1.97 [-2.47 , -1.46]	_ <b>_</b>	
Monticone 2016	1.4	1.2	75	4.5	1.8	75	3.7%	-2.02 [-2.41 , -1.62]		
Monticone 2017	2.1	0.9	85	5.3	1.5	85	3.7%	-2.58 [-2.98 , -2.17]		
Nicholas 2013	4.6	2.1	49	5.3	2.1	53	3.7%	-0.33 [-0.72, 0.06]		
Smeets 2006	42.3	25.6	55	44.6	28.9	52	3.7%	-0.08 [-0.46 , 0.30]	_	
Tavafian 2011	-65.8	22.6	92	-56.4	23.6	97	3.9%	-0.40 [-0.69 , -0.12]	-	
Thieme 2006	3.5	1	42	3.8	1.1	40	3.6%	-0.28 [-0.72, 0.15]		
Thorn 2011	5.3	2.4	32	4.6	2.3	29	3.5%	0.29 [-0.21, 0.80]	_ <b>_</b>	
Thorn 2018	5.4	2.3	83	5.7	2	80	3.9%	-0.14 [-0.45 , 0.17]	-	
Thorsell 2011	7.2	2.9	52	8	2.5	38	3.6%	-0.29 [-0.71, 0.13]		
Turner 2006	5.2	1.9	72	5.2	2.1	76	3.8%	0.00 [-0.32, 0.32]		
Vitiello 2013	4.3	3.5	232	4.2	2.9	122	4.0%	0.03 [-0.19, 0.25]	+	
Vlaeyen 1996	1	1.8	42	0.4	1.8	30	3.5%	0.33 [-0.14 , 0.80]		
Zautra 2008	32.5	19.3	51	27.5	18	40	3.7%	0.26 [-0.15, 0.68]		
van Eijk 2013	5.5	2.1	108	5.5	2.1	95	3.9%	0.00 [-0.28 , 0.28]	+	
Total (95% CI)			2017			1718	100.0%	-0.33 [-0.56 , -0.10]		
Heterogeneity: $Tau^2 = 0$	0.32; Chi <sup>2</sup> = 2	93.71, df =		.00001); I <sup>2</sup>	= 91%				•	
Test for overall effect:	,	,		,,				-	-2 -1 0 1 2	

Test for subgroup differences: Not applicable



## Analysis 7.2. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 2: Disability post-treatment

		СВТ		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	46.2	9.2	56	50.9	9.4	53	4.4%	-0.50 [-0.88 , -0.12]	
Ersek 2008	11.8	4.9	123	12.4	5.4	101	4.7%	-0.12 [-0.38, 0.15]	_
Greco 2004	-52.18	22.88	32	-49.13	26.72	33	4.1%	-0.12 [-0.61 , 0.37]	_
Kaapa 2006	20.9	10.1	59	21.6	11.4	61	4.5%	-0.06 [-0.42 , 0.29]	
Keefe 1990	2.06	1.29	31	2.34	1.28	35	4.1%	-0.22 [-0.70, 0.27]	
Keefe 1996	1.72	0.71	28	1.53	0.95	27	4.0%	0.22 [-0.31, 0.75]	_ <b>_</b>
Kraaimaat 1995	5.8	5.1	24	10.1	5.7	28	3.9%	-0.78 [-1.35 , -0.21]	_
Lera 2009	53.2	13.4	35	57.2	11.3	31	4.1%	-0.32 [-0.80, 0.17]	
Litt 2009	1.5	1.3	52	1.4	1.2	49	4.4%	0.08 [-0.31, 0.47]	
Lumley 2014	1.8	0.6	130	1.8	0.7	134	4.7%	0.00 [-0.24, 0.24]	+
Lumley 2017	-37.5	10.1	75	-36.6	8.5	76	4.6%	-0.10 [-0.42, 0.22]	_
Mangels 2009	21	13.6	232	21	13.1	131	4.8%	0.00 [-0.21, 0.21]	+
Monticone 2013	5	2	45	11	2.3	45	3.8%	-2.76 [-3.34 , -2.18]	_ <b>_</b>
Monticone 2016	15.5	4.8	75	25.3	5.5	75	4.4%	-1.89 [-2.28 , -1.50]	
Monticone 2017	24.3	9	85	36.7	8.4	85	4.5%	-1.42 [-1.76 , -1.08]	
Nicholas 2013	10.2	4.9	49	11.4	5.1	53	4.4%	-0.24 [-0.63 , 0.15]	
Smeets 2006	11.4	5.3	55	11.9	5.9	52	4.4%	-0.09 [-0.47 , 0.29]	_+
Favafian 2011	9	5.7	92	10.6	5.8	97	4.6%	-0.28 [-0.56 , 0.01]	-
Thieme 2006	3.6	2.3	42	4	2.1	40	4.3%	-0.18 [-0.61 , 0.25]	
Thorn 2011	8.4	2.8	32	8.6	3.4	29	4.1%	-0.06 [-0.57 , 0.44]	
Thorn 2018	5	2.7	83	5.5	2.4	80	4.6%	-0.19 [-0.50 , 0.11]	
Thorsell 2011	4.4	2.5	52	6.2	2.8	38	4.3%	-0.68 [-1.11 , -0.25]	
van Eijk 2013	3.9	3.3	108	3.9	2.1	95	4.7%	0.00 [-0.28, 0.28]	+
Total (95% CI)			1595			1448	100.0%	-0.41 [-0.64 , -0.17]	•
Heterogeneity: Tau <sup>2</sup> = (	0.29; Chi <sup>2</sup> = 2	16.25, df =	= 22 (P < 0	.00001); I <sup>2</sup>	= 90%				•
Test for overall effect:	Z = 3.39 (P =	0.0007)							-2 -1 0 1 2

Test for subgroup differences: Not applicable

Favours CBT Favours active control

## Analysis 7.3. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 3: Distress post-treatment

		CBT		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.8	2.5	56	8	1.8	53	3.9%	-0.09 [-0.47 , 0.29]	
Carson 2006	2.9	3.6	60	2.4	2.8	33	3.6%	0.15 [-0.28, 0.57]	
Ersek 2008	11.1	2.9	123	10.9	3.3	101	4.7%	0.06 [-0.20, 0.33]	<u> </u>
Greco 2004	14.86	10.07	32	16.52	11.53	33	3.2%	-0.15 [-0.64 , 0.34]	
Kaapa 2006	5.5	5.5	59	5.7	5.2	61	4.0%	-0.04 [-0.40, 0.32]	
Keefe 1990	2.59	1.65	31	2.09	0.94	35	3.2%	0.37 [-0.11, 0.86]	
Keefe 1996	1.7	0.97	28	2.48	1.57	27	2.9%	-0.59 [-1.13 , -0.05]	
Kraaimaat 1995	3.1	3.5	24	2.2	2.9	28	2.9%	0.28 [-0.27, 0.83]	<b></b>
Lera 2009	55.8	9.2	33	58.7	7.4	31	3.2%	-0.34 [-0.84, 0.15]	<b>_</b> _
Litt 2009	12.8	9.8	52	10.3	8.3	49	3.8%	0.27 [-0.12, 0.66]	
Lumley 2014	2	0.7	130	2.2	0.7	134	4.8%	-0.28 [-0.53 , -0.04]	
Lumley 2017	16.4	11.4	75	18.2	11.2	76	4.3%	-0.16 [-0.48, 0.16]	
Mangels 2009	7	7	232	7.8	7.8	131	5.0%	-0.11 [-0.32, 0.10]	
Monticone 2013	-81.1	13.8	45	-55.5	12.7	45	3.1%	-1.91 [-2.42 , -1.41]	
Nicholas 2013	6.6	7.2	49	9.9	9	53	3.8%	-0.40 [-0.79 , -0.01]	
Smeets 2006	9.1	6.5	54	7.7	6.6	52	3.9%	0.21 [-0.17, 0.59]	<b></b>
Tavafian 2011	-65.1	21.6	92	-57.7	23.3	97	4.5%	-0.33 [-0.61 , -0.04]	
Thieme 2006	2.8	1.1	42	3.6	1.3	40	3.5%	-0.66 [-1.10 , -0.21]	
Thorn 2011	17.6	12.1	32	17	10	29	3.1%	0.05 [-0.45, 0.56]	
Thorn 2018	9.1	5.8	83	9.6	6.1	80	4.4%	-0.08 [-0.39, 0.22]	
Thorsell 2011	6.6	5	52	8.2	5	38	3.6%	-0.32 [-0.74, 0.10]	
Turner 2006	8.8	9.3	72	11	10.6	76	4.3%	-0.22 [-0.54, 0.10]	
Vitiello 2013	6.5	9.3	232	6.8	9.1	122	5.0%	-0.03 [-0.25, 0.19]	
Vlaeyen 1996	13.4	5.8	42	11.9	5.8	30	3.3%	0.26 [-0.21, 0.73]	
Zautra 2008	1.3	0.3	50	1.3	0.3	40	3.6%	0.00 [-0.42, 0.42]	
van Eijk 2013	4.1	3.1	108	4.5	2.8	95	4.6%	-0.13 [-0.41 , 0.14]	-
Total (95% CI)			1888			1589	100.0%	-0.15 [-0.28 , -0.02]	
Heterogeneity: Tau <sup>2</sup> = (	0.08; Chi <sup>2</sup> = 8	5.38, df =	25 (P < 0.0	00001); I <sup>2</sup> =	71%				•
Test for overall effect:	Z = 2.28 (P =	0.02)							
Test for subgroup diffe	rences: Not a	pplicable							Favours CBT Favours active

#### Analysis 7.4. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 4: Pain follow-up

		CBT		Act	ive contro	bl		Std. Mean Difference	Std. 1	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, R	andom, 95% CI
Alda 2011	40.7	10.9	56	40.5	9.6	53	5.1%	0.02 [-0.36 , 0.39]		
Ersek 2008	5	2.1	114	4.5	2.1	103	5.2%	0.24 [-0.03, 0.50]		•
Greco 2004	2.05	0.94	32	1.87	0.95	33	4.8%	0.19 [-0.30, 0.68]		
Kaapa 2006	3.3	2.5	53	3.4	2.5	54	5.0%	-0.04 [-0.42, 0.34]		
Keefe 1990	5.22	2.08	30	5.91	1.95	35	4.8%	-0.34 [-0.83 , 0.15]		
Kraaimaat 1995	14.7	4.7	24	16.6	4.6	28	4.7%	-0.40 [-0.95 , 0.15]		
Litt 2009	2.1	1.2	52	2.7	1.3	49	5.0%	-0.48 [-0.87 , -0.08]		
Lumley 2014	2.8	1	130	2.8	1.1	134	5.3%	0.00 [-0.24, 0.24]		
Lumley 2017	4.8	1.7	75	4.9	2	76	5.1%	-0.05 [-0.37, 0.27]		
Mangels 2009	16.6	5.9	232	17.3	6.1	131	5.3%	-0.12 [-0.33, 0.10]		
Monticone 2013	1.4	1.1	45	5.3	1.2	45	4.5%	-3.36 [-4.01 , -2.71]		
Monticone 2016	2.4	1.5	75	4.2	1.6	75	5.1%	-1.15 [-1.50 , -0.81]		
Monticone 2017	2	0.8	85	5.5	1.2	85	4.9%	-3.42 [-3.89 , -2.94]		
Smeets 2006	20	10.1	53	17.4	10.6	51	5.0%	0.25 [-0.14, 0.64]		
Thieme 2006	3.2	1.4	42	4.1	1.5	40	4.9%	-0.62 [-1.06 , -0.17]		
Thorn 2011	5	2.4	28	4.6	2.1	26	4.7%	0.17 [-0.36, 0.71]		
Thorn 2018	5.8	2.2	71	6	2	68	5.1%	-0.09 [-0.43, 0.24]		
Thorsell 2011	7.6	2.2	52	7.9	2.5	38	5.0%	-0.13 [-0.55, 0.29]		
Turner 2006	3.9	2.6	72	4.7	2.3	76	5.1%	-0.32 [-0.65 , -0.00]		
Vitiello 2013	4.1	3.7	221	4	2.7	120	5.3%	0.03 [-0.19 , 0.25]		
Fotal (95% CI)			1542			1320	100.0%	-0.46 [-0.79 , -0.13]		
Heterogeneity: Tau <sup>2</sup> = (	).52; Chi <sup>2</sup> = 3	31.64, df =	= 19 (P < 0	.00001); I <sup>2</sup>	= 94%					
Test for overall effect: 2	Z = 2.74 (P =	0.006)							-100 -50	0 50 100
Test for subgroup differ	rences: Not ar	oplicable							Favours CI	

Cochrane

Librarv

		СВТ		Active control				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	48.8	9.1	56	52.8	9.2	53	5.4%	-0.43 [-0.81 , -0.05]	-
Ersek 2008	11.6	5.7	114	11.9	5.6	103	5.5%	-0.05 [-0.32, 0.21]	+
Greco 2004	-50.48	25.53	32	-50.22	23.86	33	5.2%	-0.01 [-0.50, 0.48]	+
Kaapa 2006	18.9	12.8	53	18.5	12.4	54	5.4%	0.03 [-0.35, 0.41]	+
Keefe 1990	1.69	1.16	30	2.63	1.5	35	5.2%	-0.69 [-1.19 , -0.18]	+
Kraaimaat 1995	8.1	5.6	24	10.1	6.6	28	5.1%	-0.32 [-0.87 , 0.23]	
Lera 2009	55.6	11.5	35	54.9	12.8	31	5.2%	0.06 [-0.43 , 0.54]	-
Litt 2009	1.9	1.5	52	1.4	1.1	29	5.2%	0.36 [-0.10, 0.82]	
Luciano 2014	1.8	6	130	1.8	0.6	134	5.5%	0.00 [-0.24, 0.24]	+
Lumley 2014	-39.1	9.9	75	-36.9	9.5	76	5.4%	-0.23 [-0.55, 0.09]	-
Mangels 2009	22.3	15.1	232	20.6	13.5	131	5.6%	0.12 [-0.10, 0.33]	-
Monticone 2013	1.3	1.6	45	11	2	45	4.4%	-5.31 [-6.20, -4.42]	<b></b>
Monticone 2016	11.9	3.8	75	27.7	6.4	75	5.2%	-2.99 [-3.46 , -2.52]	+
Monticone 2017	21.2	8.5	85	37.1	9	85	5.4%	-1.81 [-2.17 , -1.45]	+
Smeets 2006	11.8	5.8	53	10.9	5.7	51	5.4%	0.16 [-0.23, 0.54]	-
Thieme 2006	3.4	2	42	5.2	2.5	40	5.3%	-0.79 [-1.24 , -0.34]	-
Thorn 2011	8.2	3.3	28	9.8	9.8	26	5.1%	-0.22 [-0.75, 0.32]	-
Thorn 2018	5.6	2.7	71	6	2.4	68	5.4%	-0.16 [-0.49, 0.18]	-
Thorsell 2011	4.6	2.5	52	6	2.9	38	5.3%	-0.52 [-0.94 , -0.09]	+
Total (95% CI)			1284			1135	100.0%	-0.63 [-1.02 , -0.24]	
Heterogeneity: Tau <sup>2</sup> = 0	.70; Chi <sup>2</sup> = 3	67.02, df =	= 18 (P < 0)	.00001); I <sup>2</sup>	= 95%				•
Test for overall effect: 2	Z = 3.14 (P =	0.002)							-4 -2 0 2 4
Test for subgroup differ	ences: Not ap	pplicable							Favours CBT Favours active control

## Analysis 7.5. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 5: Disability follow-up

#### Analysis 7.6. Comparison 7: Sensitivity analysis - CBT vs active control, Outcome 6: Distress follow-up

		СВТ		Act	ive contro	ol		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.9	2.5	56	8.2	2	53	5.6%	-0.13 [-0.51 , 0.24]	-
Ersek 2008	11.2	3.1	114	10.8	2.7	103	6.2%	0.14 [-0.13 , 0.40]	
Greco 2004	15.01	10.5	32	14.17	11.64	33	5.0%	0.07 [-0.41 , 0.56]	
Kaapa 2006	5.7	4.6	53	5.8	5.7	54	5.6%	-0.02 [-0.40 , 0.36]	
Keefe 1990	2.51	1.33	30	2.92	1.94	35	5.0%	-0.24 [-0.73 , 0.25]	
Kraaimaat 1995	3.3	3.4	24	4	4.2	28	4.7%	-0.18 [-0.73 , 0.37]	
Litt 2009	10.7	7	52	11.7	9.2	49	5.6%	-0.12 [-0.51 , 0.27]	
Lumley 2014	2	0.7	130	2.1	0.7	134	6.3%	-0.14 [-0.38, 0.10]	-
Lumley 2017	17.3	11.9	75	18.5	12.1	76	5.9%	-0.10 [-0.42 , 0.22]	-
Mangels 2009	10.6	8.3	232	11.4	8.2	131	6.4%	-0.10 [-0.31 , 0.12]	-
Monticone 2013	-89.8	13	45	-54.1	11.9	45	4.4%	-2.84 [-3.43 , -2.25]	_ <b>—</b>
Smeets 2006	7.6	6.4	53	7.2	6.2	51	5.6%	0.06 [-0.32, 0.45]	
Thieme 2006	2.6	1.2	42	4.2	1.4	40	5.1%	-1.22 [-1.69 , -0.74]	<b>_</b>
Thorn 2011	17.2	11.1	28	16.8	9.7	26	4.8%	0.04 [-0.50, 0.57]	
Thorn 2018	9.7	6.7	71	10.5	6.4	68	5.9%	-0.12 [-0.45 , 0.21]	
Thorsell 2011	7.3	5.8	52	8.2	5	38	5.4%	-0.16 [-0.58 , 0.26]	
Turner 2006	8.3	9.1	72	11.4	10.1	76	5.9%	-0.32 [-0.64 , 0.00]	
Vitiello 2013	6.1	12.1	221	6.4	8.7	120	6.4%	-0.03 [-0.25 , 0.20]	+
Total (95% CI)			1382			1160	100.0%	-0.26 [-0.47 , -0.06]	
Heterogeneity: Tau <sup>2</sup> = 0	).17; Chi <sup>2</sup> = 1	08.88, df =	= 17 (P < 0)	.00001); I <sup>2</sup>	= 84%				•
Test for overall effect: 2	Z = 2.48 (P =	0.01)							-4 -2 0 2 4
Test for subgroup differ	rences: Not aj	pplicable							Favours CBT Favours active control

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
8.1 Pain post-treatment	28	2397	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.47, -0.09]
8.2 Disability post-treatment	27	2349	Std. Mean Difference (IV, Random, 95% CI)	-0.40 [-0.61, -0.20]
8.3 Distress post-treatment	25	2228	Std. Mean Difference (IV, Random, 95% CI)	-0.44 [-0.67, -0.22]
8.4 Pain follow-up	14	1499	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.57, -0.03]
8.5 Disability follow-up	14	1406	Std. Mean Difference (IV, Random, 95% CI)	-0.40 [-0.76, -0.04]
8.6 Distress follow-up	15	1581	Std. Mean Difference (IV, Random, 95% CI)	-0.49 [-0.84, -0.13]

## Comparison 8. Sensitivity analysis - CBT vs treatment as usual

#### Analysis 8.1. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 1: Pain post-treatment

	CBT			usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
Alda 2011	36.9	8.3	56	38.7	7.5	53	3.9%	-0.23 [-0.60 , 0.15]	_	
Altmaier 1992	2.05	0.74	21	2	0.89	21	3.1%	0.06 [-0.55 , 0.66]	_	
Basler 1997	4.08	2.11	36	4.18	1.37	40	3.6%	-0.06 [-0.51 , 0.39]	_	
Bliokas 2007	5.6	1.5	32	5.5	2	25	3.4%	0.06 [-0.47, 0.58]	_	
Carson 2006	14	12.7	60	14.6	9.4	35	3.7%	-0.05 [-0.47 , 0.37]	-	
Castel 2012	5.5	0.3	63	6.5	0.3	30	3.0%	-3.31 [-3.96 , -2.65]	<b></b>	
Castro 2012	5.7	1.7	48	5.3	1.1	45	3.8%	0.28 [-0.13, 0.68]		
Cherkin 2014	4.9	1.7	96	5.4	1.6	104	4.2%	-0.30 [-0.58 , -0.02]	-	
Evers 2002	14.93	5.32	30	15.35	4.55	29	3.4%	-0.08 [-0.59 , 0.43]	_	
Ferrando 2012	2.92	2.03	30	5.24	2.61	29	3.3%	-0.98 [-1.52 , -0.44]		
Garcia-Palacios 2015	22.6	6.3	30	20.7	8.3	29	3.4%	0.26 [-0.26, 0.77]		
Glombiewski 2010	4.6	1.9	65	5.7	1.7	51	3.9%	-0.60 [-0.98 , -0.23]		
Greco 2004	1.98	0.87	32	1.65	0.89	27	3.4%	0.37 [-0.15 , 0.89]	<b></b>	
Helminen 2015	36.7	20.4	50	39	19	43	3.8%	-0.12 [-0.52 , 0.29]	_	
Heutink 2012	65.2	12.7	31	67.2	16	30	3.5%	-0.14 [-0.64 , 0.37]	_	
ensen 2001	-29.9	11.75	49	-28.6	15.7	48	3.8%	-0.09 [-0.49 , 0.31]	-	
Karlsson 2015	3.88	1.05	23	3.67	0.75	24	3.2%	0.23 [-0.35 , 0.80]		
Keefe 1990	4.61	1.73	31	5.68	1.62	28	3.4%	-0.63 [-1.15 , -0.10]		
Litt 2009	1.5	1.4	32	1.2	1	22	3.3%	0.24 [-0.31, 0.78]		
Aishra 2000	42.5	15.11	24	42.53	23.56	25	3.3%	-0.00 [-0.56 , 0.56]	_	
Nicholas 2013	4.7	2.1	49	5.5	2.1	39	3.7%	-0.38 [-0.80 , 0.05]		
Puder 1988	3.19	0.89	31	3.26	0.66	38	3.5%	-0.09 [-0.56 , 0.38]	_	
Smeets 2006	37.8	24.3	55	53.4	22.6	49	3.8%	-0.66 [-1.05 , -0.26]		
Somers 2012	4.5	2.1	101	4.8	2	41	3.9%	-0.14 [-0.51, 0.22]	-	
Thorn 2018	5.4	2.3	83	6.2	1.8	78	4.1%	-0.38 [-0.70 , -0.07]		
Furner 1988	15.91	11.63	24	22.14	12.35	21	3.1%	-0.51 [-1.11 , 0.08]		
/an Koulil 2010	15.9	3.6	61	17.9	3.9	81	4.0%	-0.53 [-0.87 , -0.19]	-	
Williams 1996	60	21.7	38	68.1	20.7	31	3.5%	-0.38 [-0.86 , 0.10]		
Fotal (95% CI)			1281			1116	100.0%	-0.28 [-0.47 , -0.09]	•	
Heterogeneity: $Tau^2 = 0$ .	$20 \cdot C = 12$	2 00 46	27 (D + 0 (	0001). 12	000/			·	▼	

## Analysis 8.2. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 2: Disability post-treatment

		CBT		usual tro	eatment/w	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	46.2	9.2	56	48.6	6.8	53	4.0%	-0.29 [-0.67 , 0.08]	-=
Altmaier 1992	57.43	15.06	21	57.67	16.37	21	3.3%	-0.01 [-0.62, 0.59]	_ <b>_</b>
Basler 1997	1.63	0.87	36	1.84	0.62	40	3.8%	-0.28 [-0.73 , 0.17]	
Bliokas 2007	39.1	10.1	33	38.7	16	23	3.5%	0.03 [-0.50, 0.56]	
Castel 2012	50.7	3.4	63	64.6	3.5	30	2.9%	-4.02 [-4.75 , -3.28]	<b></b>
Castro 2012	-22.4	20.1	48	-13.5	19	45	3.9%	-0.45 [-0.86 , -0.04]	
Cherkin 2014	7.9	5.1	98	9.2	5	106	4.2%	-0.26 [-0.53 , 0.02]	-
Evers 2002	2.46	0.47	30	2.4	0.38	29	3.6%	0.14 [-0.37, 0.65]	
Ferrando 2012	0.98	1.09	30	0.99	1.21	29	3.6%	-0.01 [-0.52 , 0.50]	<u> </u>
Garcia-Palacios 2015	42.4	15.7	30	57	17.5	29	3.5%	-0.87 [-1.40 , -0.33]	-
Glombiewski 2010	3.9	2.2	65	4.4	2	51	4.0%	-0.23 [-0.60 , 0.13]	
Greco 2004	47.82	22.88	32	39.02	25.63	27	3.6%	0.36 [-0.16 , 0.88]	
Helminen 2015	35.8	21	54	38.2	20.9	47	3.9%	-0.11 [-0.50, 0.28]	-
Heutink 2012	38	25.4	31	44.2	27.6	30	3.6%	-0.23 [-0.73 , 0.27]	
Jensen 2001	-55.7	16.1	49	-58.4	19.7	48	3.9%	0.15 [-0.25, 0.55]	
Karlsson 2015	2.8	0.63	23	2.85	0.67	24	3.4%	-0.08 [-0.65 , 0.50]	
Keefe 1990	2.06	1.29	31	1.96	1.26	28	3.6%	0.08 [-0.43, 0.59]	
Litt 2009	1	1	32	1.7	1.4	22	3.4%	-0.59 [-1.14 , -0.03]	
Nicholas 2013	9.7	4.9	49	12.8	5.5	39	3.8%	-0.59 [-1.02 , -0.16]	-
Puder 1988	2.62	0.81	31	2.97	0.68	38	3.7%	-0.47 [-0.95, 0.01]	
Sharpe 2012	1.1	1.3	53	1.7	1.3	25	3.7%	-0.46 [-0.94 , 0.02]	
Smeets 2006	11.2	5.5	55	13.9	4.8	50	3.9%	-0.52 [-0.91 , -0.13]	
Somers 2012	1.3	1	101	1.6	0.8	41	4.0%	-0.32 [-0.68 , 0.05]	-
Thorn 2018	5	2.7	83	6.1	2.5	78	4.2%	-0.42 [-0.73 , -0.11]	-
Turner 1988	5.39	3.91	24	5.75	6.9	21	3.3%	-0.06 [-0.65 , 0.52]	-
Van Koulil 2010	17	4.2	61	20.2	3.8	87	4.1%	-0.80 [-1.14 , -0.46]	-
Williams 1996	15.81	11.2	38	29.65	10.82	31	3.6%	-1.24 [-1.76 , -0.72]	
Total (95% CI)			1257			1092	100.0%	-0.40 [-0.61 , -0.20]	▲
Total (95% CI) Heterogeneity: $Tau^2 = 0$	.24; Chi <sup>2</sup> = 14	9.98, df =		00001); I <sup>2</sup> =	83%	1092	100.0%	-0.40 [-0.61 , -0.20]	

Heterogeneity: Tau<sup>2</sup> = 0.24; Ch<sup>2</sup> = 149.98, df = 26 (P < 0.00001); Test for overall effect: Z = 3.84 (P = 0.0001)

Test for subgroup differences: Not applicable

-4 -2 0 2 4 Favours CBT Favours control

## Analysis 8.3. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 3: Distress post-treatment

		CBT		usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.8	2.5	56	8.2	2.3	53	4.3%	-0.17 [-0.54 , 0.21]	-
Altmaier 1992	14.19	5.61	21	14	5.92	21	3.6%	0.03 [-0.57, 0.64]	+
Bliokas 2007	12.9	10.3	31	19.8	12.5	25	3.8%	-0.60 [-1.14 , -0.06]	-
Carson 2006	2.9	3.6	60	3.9	4.5	35	4.2%	-0.25 [-0.67, 0.17]	-
Castel 2012	14.1	1.4	63	23.1	1.5	30	2.5%	-6.23 [-7.24 , -5.22]	<u> </u>
Castro 2012	-49.2	19.5	48	-44.2	21.2	45	4.2%	-0.24 [-0.65 , 0.16]	-
Cherkin 2014	3.2	2.8	96	5.3	4.3	104	4.5%	-0.57 [-0.86 , -0.29]	-
Evers 2002	9.98	4.62	30	12.85	7.87	29	3.9%	-0.44 [-0.96 , 0.08]	-=-
Ferrando 2012	0.44	0.54	30	0.63	0.93	29	3.9%	-0.25 [-0.76 , 0.26]	-
Garcia-Palacios 2015	16.6	8.5	30	19.7	10	29	3.9%	-0.33 [-0.84 , 0.18]	-
Glombiewski 2010	13.3	10.2	65	15.1	7.5	51	4.3%	-0.20 [-0.56 , 0.17]	-
Greco 2004	14.86	10.07	32	20.33	14.14	27	3.9%	-0.45 [-0.97 , 0.07]	-
Helminen 2015	5.5	4.5	54	6.1	6.3	47	4.3%	-0.11 [-0.50, 0.28]	4
Jensen 2001	-63.7	21.65	49	-64.75	18.55	48	4.2%	0.05 [-0.35 , 0.45]	+
Karlsson 2015	2.9	0.7	23	2.9	0.6	24	3.7%	0.00 [-0.57, 0.57]	+
Keefe 1990	2.59	1.65	31	3.42	1.8	28	3.9%	-0.48 [-0.99 , 0.04]	
Litt 2009	10.9	10.7	32	11	10.8	22	3.8%	-0.01 [-0.55 , 0.53]	+
Nicholas 2013	8.3	8.7	49	12.1	10.2	39	4.2%	-0.40 [-0.83 , 0.02]	-
Sharpe 2012	4.8	3.3	53	4.3	2.9	25	4.0%	0.16 [-0.32, 0.63]	+
Smeets 2006	8.3	5.4	55	9.6	7.9	49	4.3%	-0.19 [-0.58 , 0.19]	-
Somers 2012	2.4	1.5	101	2.8	1.7	51	4.4%	-0.25 [-0.59 , 0.08]	-
Thorn 2018	9.1	5.8	83	11.4	6.6	78	4.5%	-0.37 [-0.68 , -0.06]	-
Turner 1988	18.2	14.1	24	23.3	21.8	21	3.7%	-0.28 [-0.87, 0.31]	-
Van Koulil 2010	4.3	3.6	61	7.5	4.9	82	4.4%	-0.72 [-1.07 , -0.38]	+
Williams 1996	9.5	7.8	38	17.3	7	21	3.7%	-1.02 [-1.59 , -0.46]	+
Total (95% CI)			1215			1013	100.0%	-0.44 [-0.67 , -0.22]	•
Heterogeneity: Tau <sup>2</sup> = 0.	28; Chi <sup>2</sup> = 16	0.60, df =	24 (P < 0.0	00001); I <sup>2</sup> =	85%				¥
Test for overall effect: Z	= 3.81 (P = 0)	0.0001)							-4 -2 0 2 4
Test for subgroup differe	ences: Not app	plicable							Favours CBT Favours co

## Analysis 8.4. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 4: Pain follow-up

		CBT		usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	40.7	10.9	56	44.3	8.6	53	7.4%	-0.36 [-0.74 , 0.02]	-
Altmaier 1992	2.33	0.8	21	2	0.95	21	6.0%	0.37 [-0.24, 0.98]	<b></b>
Castel 2012	5.7	0.4	63	6.8	0.4	30	6.1%	-2.73 [-3.32 , -2.14]	
Cherkin 2014	4.3	2	86	5	1.8	100	7.9%	-0.37 [-0.66 , -0.08]	
Evers 2002	14.99	5.12	30	15.79	4.98	29	6.6%	-0.16 [-0.67 , 0.35]	-
Greco 2004	2.05	0.94	32	1.69	1.15	27	6.6%	0.34 [-0.17, 0.86]	+ <b>-</b> -
Haldorsen 1998	48.2	27.4	93	52.1	28.9	94	7.9%	-0.14 [-0.42, 0.15]	-
Helminen 2015	36.6	24.9	51	38	25	44	7.3%	-0.06 [-0.46 , 0.35]	-
Jensen 2001	-33.35	16.15	49	-32.85	20.05	48	7.3%	-0.03 [-0.43 , 0.37]	-
Keefe 1990	5.22	2.08	30	5.64	1.79	28	6.6%	-0.21 [-0.73, 0.30]	
Martin 2012	7.2	2.2	54	8.2	1.6	56	7.4%	-0.52 [-0.90 , -0.14]	
Somers 2012	4.2	2	92	4.6	2.1	37	7.4%	-0.20 [-0.58, 0.19]	
Thorn 2018	5.8	2.2	71	5.9	1.8	71	7.7%	-0.05 [-0.38, 0.28]	-
Van Koulil 2010	16.7	6.4	55	18.2	3.5	78	7.6%	-0.30 [-0.65 , 0.04]	-
Total (95% CI)			783			716	100.0%	-0.30 [-0.57 , -0.03]	
Heterogeneity: Tau <sup>2</sup> = 0	0.22; Chi <sup>2</sup> = 8	3.71, df =	13 (P < 0.0	00001); I <sup>2</sup> =	84%				•
Fest for overall effect:	Z = 2.17 (P =	0.03)							-4 -2 0 2
Fest for subgroup diffe	rences: Not aj	plicable							Favours CBT Favours

## Analysis 8.5. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 5: Disability follow-up

		CBT		usual tre	atment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	48.8	9.1	56	53.3	7.5	53	7.4%	-0.53 [-0.92 , -0.15]	-
Altmaier 1992	52.19	19.58	21	50.71	25.95	21	6.6%	0.06 [-0.54, 0.67]	
Castel 2012	52.6	3.6	63	68.5	3.7	30	5.9%	-4.34 [-5.11 , -3.57]	_ <b>_</b>
Cherkin 2014	6.4	5.3	92	7.6	5.4	106	7.7%	-0.22 [-0.50, 0.06]	-
Evers 2002	2.42	0.47	30	2.37	0.4	29	6.9%	0.11 [-0.40, 0.62]	+
Greco 2004	49.52	25.53	32	43.05	27.3	27	6.9%	0.24 [-0.27, 0.76]	
Helminen 2015	37.5	25.4	52	34.6	24.3	45	7.3%	0.12 [-0.28, 0.51]	+
Jensen 2001	-58.2	18.65	49	-59.05	24.3	48	7.3%	0.04 [-0.36, 0.44]	+
Keefe 1990	1.69	1.16	30	1.96	1.43	28	6.9%	-0.21 [-0.72, 0.31]	
Martin 2012	5.2	1.8	54	5.9	1.8	56	7.4%	-0.39 [-0.76 , -0.01]	-
Sharpe 2012	1	1.1	53	1	1	25	7.1%	0.00 [-0.48, 0.48]	+
Somers 2012	1.3	1	92	1.3	0.9	37	7.4%	0.00 [-0.38, 0.38]	+
Thorn 2018	5.6	2.7	71	6.3	2.2	71	7.6%	-0.28 [-0.61 , 0.05]	-
Van Koulil 2010	17.3	4.3	56	21.1	4.4	79	7.5%	-0.87 [-1.22 , -0.51]	+
Total (95% CI)			751			655	100.0%	-0.40 [-0.76 , -0.04]	
Heterogeneity: Tau <sup>2</sup> = 0	0.42; Chi <sup>2</sup> = 1	36.04, df =	= 13 (P < 0	.00001); I <sup>2</sup> =	= 90%				•
Test for overall effect: 2	Z = 2.18 (P =	0.03)							-4 -2 0 2 4
Test for subgroup differ	rences: Not aj	pplicable							Favours CBT Favours con

## Analysis 8.6. Comparison 8: Sensitivity analysis - CBT vs treatment as usual, Outcome 6: Distress follow-up

		СВТ		usual tre	eatment/wa	ait list		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Alda 2011	7.9	2.5	56	8.6	2.5	53	7.0%	-0.28 [-0.66 , 0.10]	-
Altmaier 1992	16.24	4.22	21	15	6.15	21	6.2%	0.23 [-0.38, 0.84]	+
Castel 2012	15	1.3	63	23.7	1.4	30	4.5%	-6.47 [-7.52 , -5.43]	
Cherkin 2014	3.5	3.2	86	4.6	3.9	100	7.2%	-0.30 [-0.59 , -0.01]	-
Evers 2002	9.51	5.35	30	13.07	7.51	29	6.5%	-0.54 [-1.06 , -0.02]	-
Greco 2004	15.01	10.5	32	16.99	12.94	27	6.5%	-0.17 [-0.68 , 0.35]	-
Haldorsen 1998	35.4	10.3	93	36.9	9.9	94	7.2%	-0.15 [-0.43 , 0.14]	-
Helminen 2015	6	5.2	53	5.4	6.4	45	6.9%	0.10 [-0.29, 0.50]	+
Jensen 2001	-67.5	20.9	49	-61.65	26.3	48	6.9%	-0.24 [-0.64, 0.15]	-
Keefe 1990	2.51	1.33	30	3.06	1.52	28	6.5%	-0.38 [-0.90, 0.14]	-
Martin 2012	9.8	4.1	53	10.2	4.2	56	7.0%	-0.10 [-0.47 , 0.28]	-
Sharpe 2012	4.4	3.8	53	4	2.8	25	6.6%	0.11 [-0.36, 0.59]	+
Somers 2012	2.4	1.5	92	2.5	2.5	37	6.9%	-0.05 [-0.44 , 0.33]	-
Thorn 2018	9.7	6.7	71	11.6	7.1	71	7.1%	-0.27 [-0.60, 0.06]	
Van Koulil 2010	4.1	3	57	7.2	4.8	78	7.0%	-0.74 [-1.10 , -0.39]	-
Total (95% CI)			839			742	100.0%	-0.49 [-0.84 , -0.13]	▲
Heterogeneity: Tau <sup>2</sup> = 0	).43; Chi <sup>2</sup> = 1	54.83, df =	= 14 (P < 0	.00001); I <sup>2</sup> =	= 91%				•
Test for overall effect: 2	Z = 2.71 (P =	0.007)							-4 -2 0 2 4
Fest for subgroup differ	rences: Not a	oplicable							Favours CBT Favours cor

### ADDITIONAL TABLES

#### Table 1. Sensitivity analysis results

Outcome	Main analysis		Sensitivity analysis	
	Meta-analysis finding	Quality of evidence	Meta-analysis finding	Quality of evi- dence <sup>a</sup>



#### Table 1. Sensitivity analysis results (Continued)

CBT vs. AC

Pain, at the end of treatment	SMD -0.09 [95% CI -0.17 to -0.01], I <sup>2</sup> 18%	Moderate	SMD -0.33 [95% CI -0.56 to -0.10], I <sup>2</sup> 91%	Very low
Disability, at the end of treatment	SMD -0.12 [95% CI -0.20 to -0.04], I <sup>2</sup> 0%	Moderate	SMD -0.41 [95% CI -0.64 to -0.17], I <sup>2</sup> 90%	Very low
Distress, at the end of treatment	SMD -0.09 [95% CI -0.18 to -0.00], I <sup>2</sup> 42%	Moderate	SMD -0.15 [95% CI -0.28 to -0.02], I <sup>2</sup> 71%.	Very low
Pain, follow-up	SMD -0.08 [95% CI -0.19 to -0.04], I <sup>2</sup> 35%	Moderate	SMD -0.46 [95% CI -0.79 to -0.13], I <sup>2</sup> 94%	Very low
Disability, follow-up	SMD -0.12 [95% CI -0.26 to 0.02], I <sup>2</sup> 53%	Low	SMD -0.63 [95% CI -1.02 to -0.24], I <sup>2</sup> 95%	Very low
Distress, follow-up	SMD -0.13 [-95% CI -0.25 to -0.01], I <sup>2</sup> 48%	Moderate	SMD -0.26 [95% CI -0.47 to -0.06], I <sup>2</sup> 84%	Very low
CBT vs TAU				
Pain, at the end of treatment	SMD -0.22 [95% CI -0.33 to -0.10], I <sup>2</sup> 50%	Moderate	SMD -0.28 [95% CI -0.47 to -0.09], I <sup>2</sup> 80%	Very low
Disability, at the end of treatment	SMD -0.32 [95% CI -0.45 to -0.19], I <sup>2</sup> 61%	Low	SMD -0.40 [95% CI -0.61 to -0.20], I <sup>2</sup> 83%	Very low
Distress, at the end of treatment	SMD -0.34 [95% CI -0.44 to -0.24], I <sup>2</sup> 36%	Moderate	SMD -0.44 [95% CI -0.67 to -0.22], I <sup>2</sup> 85%	Very low
Pain, follow-up	SMD -0.16 [95% CI -0.27 to -0.04], I <sup>2</sup> 23%	Moderate	SMD -0.30 [95% CI -0.57 to -0.03], I <sup>2</sup> 84%	Very low
Disability, follow-up	SMD -0.21 [95% CI -0.37 to -0.05], I <sup>2</sup> 57%	Low	SMD -0.40 [95% CI -0.76 to -0.04], I <sup>2</sup> 90%	Very low
Distress, follow-up	SMD -0.25 [95% CI -0.37 to -0.13], I <sup>2</sup> 36%	Moderate	SMD -0.49 [95% CI -0.84 to -0.13], I <sup>2</sup> 91%	Very low

AC: Active control; CBT: Cognitive behavioural therapy; CI: Confidence interval; SMD: Standardised mean difference; TAU: Treatment as usual

<sup>*a*</sup>We downgraded all sensitivity analyses three times to very low-quality evidence. We downgraded outcomes twice for very serious inconsistency (high heterogeneity) and once for serious imprecision (wide confidence intervals).

#### APPENDICES

#### **Appendix 1. Search strategies**

### **CENTRAL (CRSO)**

#1 MESH DESCRIPTOR Psychotherapy EXPLODE ALL TREES

#2 MESH DESCRIPTOR Cognitive Therapy EXPLODE ALL TREES

#3 MESH DESCRIPTOR Behavior Therapy EXPLODE ALL TREES



- #4 MESH DESCRIPTOR Biofeedback, Psychology
- #5 (behavio?r\* therapy) or (behavio?r\* therapies)
- #6 (cognitive therapy) or (cognitive therapies)
- #7 (relax\* adj2 (technique\* or therapy or therapies))

#8 meditat\*

- #9 psychotherap\*
- #10 (psychological adj (treatment\* or therapy or therapies))
- #11 "group therapy"
- #12 "self-regulation training"
- #13 ("coping skill\*"):TI,AB,KY
- #14 (pain-related thought\*):TI,AB,KY
- #15 (psychoeducation\* group\*)
- #16 (behavio?r\* adj2 rehabilitat\*)
- #17 (psycho-education\* group\*)
- #18 (mind adj2 body relaxation technique\*)
- #19 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
- #24 MESH DESCRIPTOR pain EXPLODE ALL TREES
- #25 MESH DESCRIPTOR Fibromyalgia EXPLODE ALL TREES
- #26 (chronic adj2 pain\*):TI,AB,KY
- #27 (((chronic adj2 (discomfort or ache\* or neuralgi\* or dysmenorrhea)))):TI,AB,KY
- #28 fibromyalgia\*:TI,AB,KY
- #29 #24 OR #25 OR #26 OR #27 OR #28
- #30 #19 AND #29
- #31 2011 TO 2020:YR
- #32 #30 AND #31

#### MEDLINE

- 1. exp PAIN/
- 2. (chronic adj2 pain\*).tw.
- 3. (chronic adj2 (discomfort or ache\* or neuralgi\* or dysmenorrhea)).tw.
- 4. exp fibromyalgia/
- 5. fibromyalgia\*.tw.
- 6. 1 or 2 or 3 or 4 or 5
- 7. exp Psychotherapy/
- 8. Cognitive Therapy/
- 9. exp Behavior Therapy/



- 10. Biofeedback/
- 11. (behavio#r\* therapy or behavio#r\* therapies).tw.
- 12. (cognitive therapy or cognitive therapies).tw.
- 13. (relax\* adj2 (technique\* or therapy or therapies)).tw.
- 14. meditat\*.tw.
- 15. psychotherap\*.tw.
- 16. (psychological adj (treatment\* or therapy or therapies)).tw.
- 17. "group therapy".tw.
- 18. "self-regulation training".tw.
- 19. coping skill\*.tw.
- 20. pain-related thought\*.tw.
- 21. (behavio#r\* adj2 rehabilitat\*).tw.
- 22. psychoeducation\* group\*.tw.
- 23. psycho-education\* group\*.tw.
- 24. (mind adj2 body relaxation technique\*).tw.
- 25. or/7-24
- 26. randomized controlled trial.pt.
- 27. controlled clinical trial.pt.
- 28. randomized.ab.
- 29. placebo.ab.
- 30. drug therapy.fs.
- 31. randomly.ab.
- 32. trial.ab.
- 33. or/26-32
- 34. exp animals/ not humans.sh.
- 35. 33 not 34

36. (201109\* or 201110\* or 201111\* or 201112\* or 2012\* or 2013\* or 2014\* or 2015\* or 2016\* or 2017\* or 2018\* or 2019\* or 2020\*).ed

- 37.35 and 36
- Embase
- 1. exp PAIN/
- 2. (chronic adj2 pain\*).tw.
- 3. (chronic adj2 (discomfort or ache\* or neuralgi\* or dysmenorrhea)).tw.
- 4. exp fibromyalgia/
- 5. fibromyalgia\*.tw.
- 6. 1 or 2 or 3 or 4 or 5



- 7. exp Psychotherapy/
- 8. Cognitive Therapy/
- 9. exp Behavior Therapy/
- 10. Biofeedback/
- 11. (behavio#r\* therapy or behavio#r\* therapies).tw.
- 12. (cognitive therapy or cognitive therapies).tw.
- 13. (relax\* adj2 (technique\* or therapy or therapies)).tw.
- 14. meditat\*.tw.
- 15. psychotherap\*.tw.
- 16. (psychological adj (treatment\* or therapy or therapies)).tw.
- 17. "group therapy".tw.
- 18. "self-regulation training".tw.
- 19. coping skill\*.tw.
- 20. pain-related thought\*.tw.
- 21. (behavio#r\* adj2 rehabilitat\*).tw.
- 22. psychoeducation\* group\*.tw.
- 23. psycho-education\* group\*.tw.
- 24. (mind adj2 body relaxation technique\*).tw.
- 25. or/7-24
- 26. random\$.tw.
- 27. factorial\$.tw.
- 28. crossover\$.tw.
- 29. cross over\$.tw.
- 30. cross-over\$.tw.
- 31. placebo\$.tw.
- 32. (doubl\$ adj blind\$).tw.
- 33. (singl\$ adj blind\$).tw.
- 34. assign\$.tw.
- 35. allocat\$.tw.
- 36. volunteer\$.tw.
- 37. Crossover Procedure/
- 38. double-blind procedure.tw.
- 39. Randomized Controlled Trial/
- 40. Single Blind Procedure/

41. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40



42. (animal/ or nonhuman/) not human/

43. 41 not 42

44. 6 and 25 and 43

45. (201109\* or 201110\* or 201111\* or 201112\* or 2012\* or 2013\* or 2014\* or 2015\* or 2016\* or 2017\* or 2018\* or 2019\* or 2020\*).dd.

46. 44 and 45

47. limit 46 to (conference abstracts or embase)

#### PsycINFO (EBSCO)

S24 S5 AND S15 AND S23

S23 S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22

S22 (singl\* OR doubl\* OR trebl\* OR tripl\*) N3 (blind\* OR mask\*)

S21 clinical N3 trial\* OR research N3 design OR evaluat\* N3 stud\* OR prospectiv\* N3 stud\*

S20 placebo\* OR random\* OR "comparative stud\*"

S19 DE "Followup Studies"

S18 DE "Placebo"

S17 DE "Treatment Outcomes" OR DE "Psychotherapeutic Outcomes" OR DE "Side Effects (Treatment)" OR DE "Treatment Compliance" OR DE "Treatment Duration" OR DE "Treatment Refusal" OR DE "Treatment Termination" OR DE "Treatment Withholding"

S16 DE "Treatment Effectiveness Evaluation"

S15 S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14

S14 (mind N2 body relaxation technique\*)

S13 pain-related thought\* OR (behavio#r\* N2 rehabilitat\*) OR psychoeducation\* group\*

S12 "group therapy" OR "self-regulation training" OR coping skill\*

S11 meditat\* OR psychotherap\* OR ( (psychological N (treatment\* or therapy or therapies)) )

S10 ( (behavio#r\* therapy or behavio#r\* therapies) ) OR ( (cognitive therapy or cognitive therapies) ) OR ( (relax\* N2 (technique\* or therapy or therapies)) )

S9 DE "Biofeedback"

S8 DE "Behavior Therapy" OR DE "Aversion Therapy" OR DE "Conversion Therapy" OR DE "Dialectical Behavior Therapy" OR DE "Exposure Therapy" OR DE "Implosive Therapy" OR DE "Reciprocal Inhibition Therapy" OR DE "Response Cost" OR DE "Systematic Desensitization Therapy"

S7 DE "Cognitive Therapy"

S6 DE "Psychotherapy" OR DE "Adlerian Psychotherapy" OR DE "Adolescent Psychotherapy" OR DE "Affirmative Therapy" OR DE "Analytical Psychotherapy" OR DE "Autogenic Training" OR DE "Brief Psychotherapy" OR DE "Brief Relational Therapy" OR DE "Child Psychotherapy" OR DE "Client Centered Therapy" OR DE "Conversion Therapy" OR DE "Couples Therapy" OR DE "Eclectic Psychotherapy" OR DE "Emotion Focused Therapy" OR DE "Existential Therapy" OR DE "Experiential Psychotherapy" OR DE "Expressive Psychotherapy" OR DE "Eye Movement Desensitization Therapy" OR DE "Feminist Therapy" OR DE "Geriatric Psychotherapy" OR DE "Individual Psychotherapy" OR DE "Individual Psychotherapy" OR DE "Individual Psychotherapy" OR DE "Individual Psychotherapy" OR DE "Interpersonal Psychotherapy" OR DE "Logotherapy" OR DE "Narrative Therapy" OR DE "Psychodynamic Psychotherapy" OR DE "Psychotherapy" OR DE "Psychodherapy" OR DE "Psychotherapy" OR DE "Solution Focused

#### S5 S1 OR S2 OR S3 OR S4



S4 fibromyalgia\* OR (chronic N2 pain\*) OR ( (chronic N2 (discomfort or ache\* or neuralgi\* or dysmenorrhea)) )

S3 DE "Fibromyalgia"

S2 DE "Pain" OR DE "Aphagia" OR DE "Back Pain" OR DE "Chronic Pain" OR DE "Headache" OR DE "Myofascial Pain" OR DE "Neuralgia" OR DE "Neuropathic Pain" OR DE "Somatoform Pain Disorder"

S1 PAIN

## WHAT'S NEW

Date	Event	Description
1 July 2020	New citation required and conclusions have changed	The new search identified 41 new studies (6255 participants) which are added to this update. We have included GRADE assess- ments in this update.
1 July 2020	New search has been performed	This review has been updated to include the results of a new search on 16 April 2020.

### HISTORY

Protocol first published: Issue 4, 2008 Review first published: Issue 2, 2009

Date	Event	Description
30 September 2019	Amended	Clarification added to Declarations of interest.
27 July 2017	Amended	Author deceased. See Published notes.
23 March 2016	Amended	Amended declarations of interest section (see Declarations of in- terest).
9 February 2016	Review declared as stable	See Published notes.
19 December 2012	Amended	Minor correction to the PLS.
13 July 2012	New search has been performed	We included 12 new trials from two new searches (Bliokas 2007; Ehrenborg 2010a; Glombiewski 2010; Leeuw 2008a; Lindell 2008; Litt 2009; Morone 2008; Schmidt 2011; Thorsell 2011; Van Koulil 2010; Wetherell 2011a; Zautra 2008). Thirty four trials included in the previous version were excluded (Astin 2003; Babu 2007; Becker 2000; Bradley 1987; Buhrman 2004 Carson 2005; Cook 1998; Dworkin 1994; Dworkin 2002b; Ersek 2003; Fairbank 2005; Flor 1993; Freeman 2002; Johansson 1998; Keefe 2004; Linton 2008; Marhold 2001; Moore 1985; Newton-John 1995; O'Leary 1988; Peters 1990; Radojevic 1992; Redondo 2004; Spence 1989; Spence 1995; Strong 1998; Turner 1990; Turner 1993; Turn- er-Stokes 2003; Vlaeyen 1995; Wicksell 2008; Woods 2008). We raised the criterion for entry from n ≥10 to n ≥20 in each arm. We added 'Risk of bias' ratings for all included studies. We also added a new outcome: catastrophic thinking.
29 March 2012	New citation required and conclusions have changed	The evidence for CBT is stronger, particularly when compared with treatment as usual/waiting list, and for mood and cata- strophic thinking. The evidence for behaviour therapy is weak



Date

Event

#### Description

or lacking. The field will not be further advanced by more small RCTs of variants of CBT for heterogeneous patient groups but by different trial and analytic methods.

#### **CONTRIBUTIONS OF AUTHORS**

AW, EF and LH sifted the search results; all authors read the selected papers; AW, EF and LH extracted data and made risk of bias ratings; AW and LH entered data into analyses; all authors judged the quality of evidence for GRADE; all authors contributed to writing and editing the manuscript.

#### DECLARATIONS OF INTEREST

AW: none known; AW is an author of an included study but was not involved in the data extraction or ratings of bias and quality for that study.

EF: none known.

LH: none known.

CE: none known. Since CE is an author as well as the PaPaS Co-ordinating Editor at the time of writing, we acknowledge the input of Andrew Moore who acted as Sign Off Editor for this review. CE had no input into the editorial decisions or processes for this review.

#### SOURCES OF SUPPORT

#### **Internal sources**

• No sources of support supplied

#### **External sources**

• Versus Arthritis Career Development Grant, UK

#### DIFFERENCES BETWEEN PROTOCOL AND REVIEW

#### Differences noted in the most recent update (2020)

In this update, we substantially revised the protocol to align with current Cochrane Review methods and reporting. The original conception of the protocol for this review was outdated, in particular lacking sections and relevant detail pertaining to risk of bias, quality of evidence, and inclusion criteria. We registered the protocol in Prospero before starting the update (Williams 2018). We have used the new protocol in the Methods section in this review. We also took into account draft guidance from the Cochrane Infectious Diseases Group, which was based on their consensus paper on how to develop a protocol for updating reviews (Garner 2016). This guidance is based on making clear the areas of change in any update that a review group editorial team will need to focus on. The protocol was reviewed by a PaPaS editor and the Managing Editor, and the Cochrane Editorial and Methods Department assessed it for quality.

The protocol made several changes from the Williams 2012 review, which this review largely updates.

(1) We removed the outcome of catastrophic thinking about chronic pain (introduced *de novo* in the 2012 review) for two reasons: we agree with current thinking about catastrophising that it is a process variable rather than an outcome variable (Burns 2012); its measurement has come under criticism for lack of conceptual clarity (Crombez, 2020). (2) We included adverse events as a primary outcome in the protocol. (3) We only included face-to-face interventions in this update, excluding remotely delivered therapies, which are summarised elsewhere (Eccleston 2014). (4) We did not, as previously, use the Yates scale for quality (Yates 2005), apart from one item, 'treatment expectations,' with a binary response of 0 or 1 for the absence or presence of any difference between groups. We decided to keep this item as a potential measure of at least one source of performance bias. The use of quality measurement is discouraged in Cochrane because such tools are often a mixture of quality and bias judgements. Additionally, our use of Yates pre-dates the adoption of GRADE in Cochrane Reviews. Here we judged that the use of the RoB tool and the use of GRADE covered most of the relevant domains. (5) We have added a separate category of treatment labelled acceptance and commitment therapy. The main reason for this addition was to align the review with current developments in psychotherapy. ACT was included in the previous reviews as a form of CBT. Although there are strong arguments for its being considered a variant of CBT, there are also strong views that its differences outweigh its similarities and that it should be considered separately (e.g. Hayes 2006). There is precedent for this approach in the Cochrane Library (Churchill 2013; Hunot 2013; Naeem 2015). Consequently, there are new analyses, specifically ACT versus AC and ACT versus TAU. (6) We have assessed quality of



evidence and included 'Summary of findings' tables in this update. (7) We abandoned subgroup analysis plans outlined in previous reviews since, as this field evolves, we did not think these were relevant or that we would ever have enough data to be able to conduct them.

Below are the changes in this review from the published protocol (Williams 2018).

- 1. We planned to include adverse events as primary outcome in the protocol, but have also reported dropout, which can indicate dissatisfaction with treatment but is not conventionally included as an adverse event.
- 2. The protocol anticipated 12 outcome analyses but, on the advice of a reviewer, we combined end-of-treatment and follow-up analyses under the same group for each comparison, giving six rather than 12 outcome analyses; each with six rather than three sub-analyses.
- 3. In the protocol, we planned a SoF table for each of CBT, BT, and ACT. The number of trials of BT and ACT were insufficient for a SoF table. Instead, we examined CBT trials in 2 tables according to control condition, AC or TAU.
- 4. We did not undertake planned sensitivity analyses by size of trial because there was insufficient variability in the range of studies for these to yield stable or meaningful results. We judged that it would therefore be misleading to perform them.
- 5. We attempted to clarify why four studies were notable outliers by contacting authors. We got no answer from the authors of one study; answers regarding the other three did not explain the effects. We therefore opted to do sensitivity analyses.

## NOTES

Author Stephen Morley sadly passed away in 2017. The review was amended and republished in July 2017 to reflect this.

#### INDEX TERMS

#### Medical Subject Headings (MeSH)

Affect; Behavior Therapy [\*methods]; Chronic Pain [psychology] [\*therapy]; Cognitive Behavioral Therapy [methods]; Randomized Controlled Trials as Topic

#### **MeSH check words**

Adult; Humans