NKR 16 Generaliserede smerter PICO 3 CBT

Characteristics of studies

Characteristics of included studies

Alda 2011

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Ang 2010

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

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Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Castel 2009

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

Bias	Authors' judgement	Support for judgement
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Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Castel 2012

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

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Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Edinger 2005

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

Bias	Authors' judgement	Support for judgement
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Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Falcao 2008

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Haldorsen 1998

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev 2012;11:CD007407.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Jensen 2012

Methods	RCT, 12 weeks intervention and 3 month FU
Participants	A total number of 82 female FM patients were referred to the study from primary care physicians. All patients were screened via telephone, and 47 of them were deemed eligible for a screening visit at the Karolinska Hospital, Stockholm, Sweden. Patients that were turned down during the telephone screening did not fulfill the inclusion criteria or were unable to participate due to the practical aspects of the study protocol. After the screening visit, 43 patients fulfilled the inclusion criteria and were enrolled in the study (Fig. 1). The mean age was 45.6 years (SD 6.4) and, on average, patients had suffered from FM pain for 11 years (SD 6.7). The inclusion criteria required that patients were 18-55 years of age, female, diagnosed with FM and referred to the study by their primary care physician. To be eligible for the study, all patients had to fulfill the 1990 American College of Rheumatology diagnostic criteria [59] at screening and report a weekly pain intensity of at least 40 mm on a 0-100 visual analogue scale (VAS) anchored with no pain and worst possible pain (Table 1). All patients were screened by an experienced pain clinician (D.K.). Moreover, patients had to fit the criteria for fMRI examinations, excluding all left-handed, pregnant, or breastfeeding patients, as well as patients with metal implants or claustrophobia
Interventions	Intervention: The CBT program consisted of 12 weekly sessions (approximately 90 minutes each) and was conducted in groups of 6 patients. More specifically, the protocol was based on ACT, pertaining to the third generation of CBT interventions. The treatment program had previously been used for different types of chronic pain, and more details can be found in 2 recent publications [55,56]. However, a brief description of the clinical model is provided. In ACT [22], avoidance of pain and distress is conceptualized as a core problem that substantially contributes to disability and reduced quality of life. According to the theory underlying ACT, avoidance occurs primarily when negative thoughts and emotions have excessive or inappropriate impact on behavior (denoted as cognitive fusion). The core intervention is considered to be exposure to personally important situations and activities that have been previously avoided due to pain and distress, in order to develop new behavioral responses. In contrast to most treatments, which emphasize reduction or control of symptoms, ACT promotes acceptance of negative reactions that cannot be directly changed (thoughts, emotions, bodily sensations) in favor of engaging in activities that are meaningful, though possibly painful or fear provoking (ie, exposure). As part of this process, the patient is also trained to distance him/herself from pain and distress in order to decrease the impact of these experiences on behavior (cognitive de-fusion). In short, ACT seeks to improve functioning and quality of life by increasing psychological flexibility, defined as the ability to act effectively in accordance with personal values in the presence of interfering thoughts, emotions, and bodily sensations [22]. The study psychologists (R.W., M.K.) conducted 10 sessions, and a physician specialized in pain (G.O.) conducted 2 sessions. The 2 psychologists involved in the intervention were trained in CBT. Both the psychologists and the physician had experience, as well as formal training, in ACT. Treatment content followed a clearly written protocol, and patient progress was discussed continuously to maintain treatment fidelity. Control: Waiting list
Outcomes	Pain, Depression, Anxiety, Drop-out

Identification	Jensen KB, Kosek E, Wicksell R, Kemani M, Olsson G, Merle JV, et al. Cognitive Behavioral Therapy increases pain-evoked activation of the prefrontal cortex in patients with fibromyalgia. Pain 2012 Jul;153(7):1495-1503.
Notes	Sweden. Funding:KJ received support from the Swedish Society for Medical Research (SSMF) and the Swedish Council for Working Life and Social Research. EK received support from the Swedish research council, project # K2009-53X-21070-01-3 and Stockholm County Council. Also, EK and GO were supported by the Swedish Rheumatism Association

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization list. A research assistant who was not involved in the study generated the allocation sequence
Allocation concealment (selection bias)	Low risk	The sequence was concealed until interventions were assigned. The patients agreed to participate before random allocation and without knowing which reatment they would receive
Blinding of participants and personnel (performance bias)	High risk	Not blinded
Blinding of outcome assessment (detection bias)	High risk	Particpants are assessors and are not blinded
Incomplete outcome data (attrition bias)	Unclear risk	equal dropout rate in each group
Selective reporting (reporting bias)	Low risk	All results are provided
Other bias	Low risk	No other bias

Karlsson 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age, mean (SD)*: 48.3 (11,5) ● *Gender, female n(%)*: 24 (100%) ● *In gainful work n (%)*: 7 (29,2) ● *No of tenderpoints*: 16 (2.56) ● *On analgetic drugs, continuously or intermittent n(%)*: 16 (66.7 Kontrol ● *Age, mean (SD)*: 48.8(6.50) ● *Gender, female n (%)*: 24(100%) ● *In gainful work n (%)*: 12 (50) ● *No of tenderpoints*: 15.5 (2.30 ● *On analgetic drugs, continuously or intermittent n(%)*: 16 (66.7) Overall ● *Gender, female n(%)*: 48 (100%) **Included criteria:** Age18–64 years, being Swedish-speaking, and fulfilment of the 1990 ACR criteria, (generalized pain for more than three months, distributed in all four body quadrants, and at least 11 tenderpoints in typical locations) **Excluded criteria:** Major psychiatric or somatic disease, and substance abuse **Pretreatment:** There were no significant differences between the two groups in baseline variables
Interventions	**Intervention Characteristics** Intervention ● *Description*: CBT stress management programme ● *Duration (weeks)*: 6 months ● *Dose, (e.g no of sessions)*: 20 sessions of 3 hours duration every weeks pluss 3 booster sessions of 3 hours duration during the next 6 months Kontrol ● *Description*: Waiting list ● *Duration (weeks)*: 6 months ● *Dose, (e.g no of sessions)*: Waiting list received the same CBT program after intervention group had completed program
Outcomes	*Funktionsevne, Final, MPI-3 (mean, SD)* ● **Outcome type**: ContinuousOutcom *Smerter, final, MPI-1, pain severity, mean (SD)* ● **Outcome type**: ContinuousOutc *Frafald, final, n* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** 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) **Country:** Sweden **Setting:** A municipality in Sweden **Authors name:** Bo Karlsson

	Institution: Uppsala University, Department of Public Health and Caring Sciences, Family Medicine and Preventive Medicine Section, Uppsala, Sweden **Email:** bo.karlsson@pubcare.uu.se **Address:** Department of Public Health and Caring Sciences, P.O.Box 564, SE-75122 Uppsala, Sweden.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "chart of the study population. function 'ranuni' that produces random numbers with equal distri- bution, i.e. all numbers appear with the same probability. According to this design for every four consecutive patients two were ran- domly allocated to group 1 and the remaining two were allocated to group 2. The allocations were indicated on" Judgement Comment: The SAS Function Ranuni was applied for random allocation
Allocation concealment (selection bias)	Low risk	Quote: "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 disturbing 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 corresponding serial number envelope was opened and the patient allocation was noted in the study chart."
Blinding of participants and personnel (performance bias)	High risk	Quote: "The patients' local physicians were informed about the study and were responsible for the every-day care of the patients.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: "Self-reported measurements"
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: "Low dropout in each group"
Selective reporting (reporting bias)	Low risk	Judgement Comment: "It seems that the published reports include all of the expected outcomes"
Other bias	Low risk	Judgement Comment: no conflicts of interest

Lami 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age, mean (SD)*: 49.35 (6.43) ● *Gender, female n(%)*: 34 (100) ● *In gainful work n (%)*: 44.1 ● *On analgetic drugs, continuously or intermittent n(%)*: 79.4 Kontrol ● *Age, mean (SD)*: 51.37 (9.38) ● *Gender, female n(%)*: 41 (100) ● *In gainful work n (%)*: 32.2 ● *On analgetic drugs, continuously or intermittent n(%)*: 70.7 Overall ● *Age, mean (SD)*: 50.19 (8.24) ● *Gender, female n(%)*: 113 (100) ● *In gainful work n (%)*: 38. ● *On analgetic drugs, continuously or intermittent n(%)*: 77.9 **Included criteria:** Women between 25 - 65, meeting ACR criteria for FM for more than 6 months, being stable in regards to the intake of analgesics, antidepressants, or other drugs, sleep and pain, at least 1 month before the study and not being treated with another psychological therapy, and meeting the diagnostic criteria for insomnia **Excluded criteria:** Major concomitant medical conditions (e.g inflammatory rheumatic disease, endocrine disturbances, neurological disorder, cancer, recent surgery), pregnant, metal disorders with severe symptoms (e.g. major depression with suicide ideation schizophrenia, personality disorder, or other organic sleep disorder i.e. apnea having severe dependence of hypnotic drugs and having irregularities in circadian rhythms at the tame of the study **Pretreatment:** Groups did not differ in any baseline measures
Interventions	**Intervention Characteristics** Intervention ● *Description*: 2 sessions: 1: Onset and course of FM and insomnia, patients life history, lifestyle, work activity family and social relationships, and psychological state 2, Obtain additional data abut insomnia, collect questionnaires answer questions related to treatment, sleep-diary for 2 weeks. CBT Paln program: Information about the FM-syndrome and pain, the treatment program and the active role of the participant, Relaxation breathing and training, identifying unpleasant emotional states. emotions and pain, management of emotions and fear of pain, planning activities, activity and rest, communication and relationship with others, assertive communication training, Training in problem solving skills, CBT1: Identification of dysfunctional thoughts/attitudes related to pain, related to pain (e.g. catastrophizing) CBT2, Strategies to replace dysfunctional thoughts/attitudes with more adaptive ones, cognitive restructuring, integration of treatment components, maintenance of gains, anticipation of possible relapses planning future evaluation.

	● *Duration (weeks)*: 9 weeks ● *Dose, (e.g no of sessions)*: 9 (90 min. sessions) once a week Kontrol ● *Description*: 2 sessions: 1: Onset and course of FM and insomnia, patients life history, lifestyle, work activity family and social relationships, and psychological state 2, Obtain additional data abut insomnia, collect questionnaires answer questions related to treatment, sleep-diary for 2 weeks ● *Duration (weeks)*: 9 weeks ● *Dose, (e.g no of sessions)*: 0
Outcomes	*Smerter, final, PVAS; mean (SD)* ● **Outcome type**: ContinuousOutcome *frafald, final, n* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** The Spanish Ministry of Science and Innovation and the Spanish Ministry of Economy and Competitiveness **Country:** Spain **Setting:** Hospital **Authors name:** María J. Lami **Institution:** Department of Personality, Assessment and Psychiologic Treatment, University of Granada, Gradana, Spain **Email:** mjlamih@correo.ugr.es
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: A number generator was used to allocate participants randomly to the treatments No description on how the randomization was performed. However they describe that a number of generators was used by a researcher blinded to the implementation of the trial.
Allocation concealment (selection bias)	Low risk	Judgement Comment: The researcher conducting the number generator was blinded to the implementation of the trial
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: The study did not address this outcome
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: "self-reported measurements"
Incomplete outcome data (attrition bias)	High risk	Judgement Comment: No ITT and high dropout rates
Selective reporting (reporting bias)	Low risk	Judgement Comment: It seems that the rport includes all expected outcomes
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Lazaridou 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Overall ● *Age, mean (SD)*: 45.7 (12.2) ● *Gender, female n(%)*: 82,9 % ● *In gainful work n (%)*: 27.1 % **Included criteria:** (1) At least 18 years old, (2) documented presence of rheumatologist-diagnosedFM for at least 1 year, (3) meet the revised Wolfeet al 34 ACR criteria for FM, and (4) score on the PCSof at least 21. **Excluded criteria:** (1) History of clinically significantanxiety symptoms interfering with fMRI procedures(eg, claustrophobia, panic disorder), (2) recenthistory of cardiac events such as myocardial infarction,(3) history of significant head injury, (4) peripheral neuropathy, (5) use of certain centrallyacting analgesic medications such as opioids, (6) history of substance abuse, (7) concurrent autoimmuneor inflammatory disease, (8) implantedmetallic objects, (9) pregnancy, (10) diseases affectingthe central nervous system (eg, multiple sclerosis, Parkinson's disease), (11) serious psychiatric conditionsprecluding participation (eg, psychoticdisorders). **Pretreatment:** The Education and CBTgroups did not differ at baseline in BPI, PCS, or BDIscores.
Interventions	**Intervention Characteristics** Intervention ● *Description*: CBT Treatment sessions used active, structured techniquesto alter distorted thoughts, with a focus on acquiring andpracticing cognitive and emotion-regulation skills. CBTwas based on a pain self-management paradigm, andinvolved the identification and reduction of maladaptivepain-related cognitions (ie, catastrophizing) using techniquessuch as relaxation, visual imagery, thought challenging,and distraction. CBT prominently emphasized in vivopractice during each session, and featured home practiceusing written exercises. In particular, cognitive restructuringwas used to help patients recognize the relationshipsbetween thoughts, feelings, and behaviors. Patients learnedto identify, evaluate, and challenge negative thoughts andto diminish the degree of catastrophizing about pain. ● *Duration (weeks)*: 4 weeks ● *Dose, (e.g no of sessions)*: 4 sessions (60-70 minutes) Kontrol

	● *Description*: EducationThis condition, matched for amount of professionalcontact, included information about FM and about chronicpain. The sessions provided a variety of information aboutthe nature and presumed causes of FM, but they involvedno active skills training or homework assignments. Educationis often utilized as an active control condition thatprovides a comparator in CBT in controlled trials.42 Thiseducational intervention was developed to control forimportant nonspecific factors related to therapist attentionand outcome expectancy, as well as natural history andregression to the mean. ● *Duration (weeks)*: 4 weeks ● *Dose, (e.g no of sessions)*: 4 sessions (60-70 minutes)
Outcomes	*Smerter, BPI, mean change (SD)* ● **Outcome type**: ContinuousOutcome *frafald, final, n* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Supported by NIH grant R01-AR064367, by grants to RRE from theArthritis Foundation and the American College of Rheumatologyand grant P01-AT006663, R01-AT007550 to VN by the NationalCenter for Complementary and Integrative Health (NCCIH). Theproject was carried out in part at the Athinoula A. Martinos Centerfor Biomedical Imaging at the Massachusetts General Hospital,Charlestown, MA, using resources provided by the Center forFunctional Neuroimaging Technologies, P41EB015896, a P41Biotechnology Resource Grant supported by the National Instituteof Biomedical Imaging and Bioengineering (NIBIB), NationalInstitutes of Health and the KIOM grant K16051. **Country:** USA **Setting:** Outpatient clinic **Authors name:** Asimina Lazaridou **Institution:** Departments of Anesthesiology; yMedicine, Division of Rheumatology, Harvard Medical School, **Email:** RREdwards@partners.org **Address:** Robert R. Edwards, PhD, Brigham Women's Hospital,Pain Management Center, 850 Boylston St., Chestnut Hill, MA02467 USA
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Judgement Comment: No describtion how randomization was performed Insufficient information about the sequence generation to permit judgement of low or high risk
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Study participants were informed that they would be randomized to receive "one of two behavioral interventionsto improve quality of life in fibromyalgia patients."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Participants didnt know of the difference between the groups. Personal did know the difference
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: "It is likely that the investigator have been aware of who was allocated to what, but it is unclear wheter it has influnces outcomes Self-reported measurements"
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: All participants completed the study
Selective reporting (reporting bias)	Low risk	Judgement Comment: It is my understandig that the report include all the expected outcomes
Other bias	High risk	Judgement Comment: The study might be underpowered due to few participants (8+8)

Luciano 2014

Methods	RCT 8 sessions, 6 months follow up
Participants	FM patients were recruited from primary health care centers in Zaragoza, Spain. The patients considered for inclusion were aged 18 to 65 years who could speak and read Spanish fluently and who fulfilled the ACR 1990 criteria for FM at screening, with no pharmacological treatment (or agreed to discontinue use to participate in the study) and no previous psychological treatment during the previous year
Interventions	Intervention: Group based ACT (GACT): This intervention was based on the original program [53] adapted to FM patients. One therapist (JAG) delivered the structured intervention, comprising eight 2.5 h sessions with groups ranging from 10 to 15 patients. The sessions covered specific exercises and topics within the context of ACT practice and training, including various types of formal mindfulness practice (Table 1). At enrollment, the participants were asked to commit to daily homework assignments of 15 to 30 min. The therapist was an experienced clinical psychologist trained in ACT and group management, with clinical experience treating FM patients. All sessions were videorecorded, and 2 authors (YLdH and BO) randomly reviewed 2 sessions in each group of ACT to confirm that the psychological treatment followed the treatment manual. Control: Waiting list, Patients randomized to this condition received no active treatment over the study period but were offered their preferred intervention at the conclusion of the study.
Outcomes	Quality of life, pain, depression, anxiety, catastrophizing, drop-out
Identification	Luciano JV, Guallar JA, Aguado J, Lopez-Del-Hoyo Y, Olivan B, Magallon R, et al. Effectiveness of group acceptance and commitment therapy for fibromyalgia: A 6-month randomized controlled trial (EFFIGACT study). Pain 2014 Apr;155(4):693-702.
Notes	Spain. Funding: Juan V. Luciano received a research contract from the Institute of Health Carlos III (Red RD06/0018/0017).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization list. A research assistant who was not involved in the study generated the allocation sequence
Allocation concealment (selection bias)	Low risk	The sequence was concealed until interventions were assigned. The patients agreed to participate before random allocation and without knowing which reatment they would receive.
Blinding of participants and personnel (performance bias)	High risk	Not possible to blind
Blinding of outcome assessment (detection bias)	High risk	Particpants are outcome assessors and not possible to blind
Incomplete outcome data (attrition bias)	Low risk	Equal dropout rate in each group
Selective reporting (reporting bias)	Low risk	All results are provided
Other bias	Low risk	No other bias

Thorsell 2011

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev 2012;11:CD007407.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Vallejo 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age, mean (SD)*: 53.5 (8.56) ● *Gender, female n(%)*: 20(100) ● *In gainful work n (%)*: 7 (35) ● *No of tenderpoints*: 999 Kontrol ● *Age, mean (SD)*: 51.33 (10.03) ● *Gender, female n(%)*: 20(100) ● *In gainful work n (%)*: 6 (30) Overall ● *Age, mean (SD)*: 51.55 (9.87) ● *Gender, female n(%)*: 60 (100) ● *In gainful work n (%)*: 21 (35) **Included criteria:** (a) meet theAmerican College of Rheumatology (ACR) research classification criteria for FM (Wolfe et al. 1990), (b) minimum 18 years of age, (c) adequate reading comprehension, and (d) access to and ability to use a computer. **Excluded criteria:** (a) diagnosed with any mental health disorder by a psychiatrist or clinical psychologist in a Public Mental Health Center or Psychiatric ServiceHospital; (b) the presence of suicidal ideation (score 1, 2 or 3 on item 9 of the Beck Depression Inventory (BDI)), (c) prior or present psychological treatment for FM or other chronic pain syndromes, or(d) scheduled for surgery in the next 3 months. **Pretreatment:** There were no significant between-group differences
Interventions	**Intervention Characteristics** Intervention ● *Description*: Each session corresponded to a module thatincluded specific content and activities according to the multidi-mensional model of pain (Turk and Sherman, 2002) and themulticomponent pain programs (Mazumdar et

	al.1999), with someadaptations for FM patients. The following principal components were used: psycho-education about FM and pain and discussion of methods to reduce the impact of FM (Session 1); progressive relaxation training (Session 2); emotional training, including breathing techniques (Session 3); increasing and adjusting daily activities to improve pain and symptomatology (Session 4); techniques for insomnia and sexual dysfunctions (Session 5); problem solving (Session 6); cognitive restructuring and managing of negative thoughts (Session 7); attentional control and illness behaviours (Session 8); intellectual problems and difficulties related to cognitive processing and memory (Session 9); and revision andrelapse prevention (Session 10). All participants completed the 10weekly sessions. The structure of the session was as follows: review of the week, including homework related to the content of the session; introducing the specific material of the session; practicing and discussing this material; and homework assignment for the next week. ● *Duration (weeks)*: 10 weeks ● *Dose, (e.g no of sessions)*: 10 sessions (120 min) Kontrol ● *Description*: All participants (WL, CBT, and iCBT groups) were patients in the Rheumatology Unit and were managed by the same rheumatologist. They received conventional pharmacology treatment on a personalised basis as appropriate ● *Duration (weeks)*: 10 weeks ● *Dose, (e.g no of sessions)*: 0
Outcomes	*Funktionsevne, SF-36 PF (mean, 95%CI)* ● **Outcome type**: ContinuousOutcome *Funktionsevne, Final, MPI-3 (mean, SD)* ● **Outcome type**: ContinuousOutcome *Funktionsevne, final, CPSS, mean (SD)* ● **Outcome type**: ContinuousOutcome *frafald, final, n* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Supported by a grant from the Instituto de la Mujer, Ministeriode Sanidad, Servicios Sociales e Igualdad, Spanish Government(Exp. 2011-INV-00232) **Country:** Spain **Setting:** Hospital **Authors name:** Miguel A. Vallejo **Institution:** Department of Clinical Psychology, National Distance Education University (UNED), Madrid, Spain **Email:** mvallejo@psi.uned.es **Address:** Faculty of Psychology, UNED, Juan del Rosal 10, 28040,Madrid, Spain
Notes	*NKR Bevægeapp* on 22/01/2018 06:50 **Outcomes** Der er ikke rapporteret 6 og 12 mdr follow up på WL group- Alternativt skal vi afrapporetere på post treatment istedet, men der er der rapporteret på koefficient og standard error. Det er templaten ikke lavet til? **Outcomes** Values given at funktionsevne, final CPSS, mean (SD) are end of treatment. There are no data on control group at any later time points.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "used a 1:1:1 randomization approach. The patients were randomly assigned by a computer-generated randomization schedule to the WL, CBT, or iCBT groups. The randomization was conducted by a research assistant. There were 2 assessment points"
Allocation concealment (selection bias)	Low risk	Judgement Comment: addressed, but assumed low, due to the computer generalised randomisation
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding of participants or personell was possible
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: The particpants are considered outcome assessors as only questionnaires were used.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: 3/20 were lost to follow up in the interventiongroup without further explanations. 0/20 were lost to follow-up in the wailing list group. Intention to treat analysis was performed.
Selective reporting (reporting bias)	Low risk	Judgement Comment: It seems that the published reports include all of the expected outcomes
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Van Koulil 2010

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev 2012;11:CD007407.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Vlayen 1996

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev 2012;11:CD007407.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Wetherell 2011

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev 2012;11:CD007407.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Following the pretreatment assessment, an independent researcher with no insight or involvement in the treatment intervention conducted the randomization using prepared and sealed envelopes with codes for the different study conditions
Blinding of participants and personnel (performance bias)	High risk	Not blinded
Blinding of outcome assessment (detection bias)	High risk	Participants are outcomes assesors and are not blinded

Incomplete outcome data (attrition bias)	Unclear risk	Intervention 4 out of 23 dropped out, control 3 out of 17 dropped out
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	No other bias

Wicksell 2013

Methods	RCT, 3 month FU
Participants	Female patients between 18 and 55 years old, fulfilling the American College of Rheumatology classification criteria for FM (Wolfe et al., 1990), and with a weekly self-reported average pain intensity of > 40 (visual analogue scale 0 100), were considered eligible for inclusion in the study. Because functional magnetic resonance imaging (fMRI) exams were performed as part of the research project, all left-handed, pregnant or breastfeeding patients as well as patients with metal implants or claustrophobia were excluded. Also, the use of treatments that could influence the patients pain perception, such as antidepressants and mood stabilizers, analgesics, strong opioids, anticonvulsants, centrally acting relaxants, joint injections, trigger/tender point injections, biofeedback and transcutaneous electrical nerve stimulation, was considered incompatible with participation and had to be discontinued before entering the study. However, small doses of non-steroidal anti-inflammatory drugs were allowed as rescue medication (if discontinued 48 h prior to any study assessments).
Interventions	Intervention: The ACT intervention consisted of 12 weekly group sessions (90 min each), with 6 participants in each group. Psychologists conducted 10 sessions, and a physician conducted the remaining 2. The two psychologists and the physician who delivered the treatment had training in CBT as well as training and previous experience of using ACT. The intervention followed a clearly written protocol. Treatment content and patient progress were discussed continuously to maintain treatment fidelity. Furthermore, videotaped sessions were analysed to formally assess treatment integrity (see below). If unable to attend a group session, an individual 30-min summary of the missed session was provided prior to the next session. Also, absence from five sessions resulted in exclusion from the study as well as discontinuation of the treatment program. According to ACT theory (Hayes et al., 2006), a narrow and inflexible behaviour pattern characterized by avoidance of pain and distress (i.e., psychological inflexibility) may play a central role in the development of disability and reduced quality of life. The experienced need to avoid psychological events occurs when verbal processes have excessive or inappropriate impact on behaviours, a process denoted as cognitive fusion. Exposure to personally important situations and activities that have been previously avoided due to ongoing or anticipated pain and distress is considered central to treatment and primarily aimed at the acquisition of new behavioural responses. The objective is not to reduce pain or related symptoms, but to increase the ability to act in accordance with personally held values also in the presence of interfering pain and distress (i.e., psychological flexibility). Acceptance (or willingness to experience) is promoted as a behavioural response to pain and distress that cannot be directly changed. Also, the patient learns to step back from thoughts, or in other words to disengage from verbal processes, to decrease the impact of thoughts on behaviour (cognitive defusion). The ACT intervention was organized into four phases, with relatively distinct treatment objectives. In short, the content of the treatment was as follows. In phase 1 (preparing for behavioural change), the dysfunctional character of long-standing pain syndromes was discussed to alter the context in which pain avoidance occurs and to initiate a shift in perspective from symptom reduction to valued living. Phase 2 (shifting perspective) focused on clarification of individual life values. This was combined with an exercise in which the workability of previous strategies to reduce pain and improve functioning was thoroughly evaluated. In essence, the discussion of values and workability of previous strategies served to illustrate the possibility of increasing functioning and life quality by accepting a certain amount of pain and distress. In phase 3 (values-oriented behaviour activation), shortand long-term behavioural goals were defined based on identified life values, followed by a discussion of how to gradually increase previously avoided activities. Phase 4 (acceptance and cognitive defusion) emphasized the utility of a more flexible behavioural repertoire in relation to pain and distress. The participants were encouraged to notice and remain open to unpleasant private experiences when doing so served valued ends. Illustrations and metaphors were commonly used to clarify central concepts, such as psychological flexibility. In-session exercises characterized by exposure to pain and distress provided opportunities for direct experiential learning. Acceptance and defusion strategies were practiced by the participants during in-session exercises as well as in homework assignments carried out between sessions. The ACT intervention was functionally similar to the treatment content described in detail in previous papers (Wicksell et al., 2005, 2008a, 2009, 2007). However, this was the first study to evaluate the protocol as provided using a group format. The full protocol can be retrieved from the first author. Control: Waiting list
Outcomes	Disability, quality of life, pain, depression, anxiety, drop-out
Identification	Wicksell RK, Kemani M, Jensen K, Kosek E, Kadetoff D, Sorjonen K, et al. Acceptance and commitment therapy for fibromyalgia: A randomized controlled trial. European Journal of Pain Apr 2013;17(4):599-611.
Notes	Sweden. Funding: One author (E. K.) received support from the Swedish Research Council, Project No. K2009-53X-21070-01-3, the Stockholm County Council, and the Swedish Rheumatism Association.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Woolfolk 2012

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	Bernardy K, Klose P, Busch Angela J, Choy Ernest HS, Häuser W. Cognitive behavioural therapies for fibromyalgia. Cochrane Database Syst Rev 2013;9:CD009796.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Footnotes

Characteristics of excluded studies

Agoston 2016

Reason for exclusion	Wrong patient population

Baranoff 2016

Reason for exclusion	Wrong patient population

Bawa 2015

Reason for exclusion	Wrong intervention

Castel 2014

Reason for exclusion	Wrong outcomes

Cedraschi 2015

Reason for exclusion	Wrong intervention

Chou 2017

Reason for exclusion	Wrong study design

Christensen 2015

Reason for exclusion	Wrong outcomes

Coretti 2014

Reason for exclusion	Wrong outcomes

Costa 2015

Reason for exclusion	Wrong study design

COUPLAND 2016

Reason for exclusion	Wrong patient population

Doherty 2016

Reason for exclusion	Wrong comparator

Finan 2014

Reason for exclusion	Wrong patient population

Fitzcharles 2014

Reason for exclusion	Wrong intervention

Hauser 2014

Reason for exclusion	Wrong study design

IsmaelMartins 2014

Reason for exclusion	Wrong intervention

Jacobsen 2015

Reason for exclusion	Wrong study design

Jones 2017

Reason for exclusion	Wrong route of administration

Kemani 2015

Reason for exclusion	Wrong patient population

Ljotsson 2014

Reason for exclusion	Wrong study design

Lumley 2016

Reason for exclusion	Wrong outcomes

Lumley 2017

Reason for exclusion	Wrong intervention

Macfarlane 2016

Reason for exclusion	Wrong study design

Martin 2014

Reason for exclusion	Wrong intervention

Menga 2014

Reason for exclusion	Wrong outcomes

Nes 2017

Reason for exclusion	Wrong route of administration

Papadopoulou 2016

Reason for exclusion	Wrong intervention

Steiner 2014

Reason for exclusion	Wrong study design

Thieme 2016

Reason for exclusion	Wrong outcomes

Wilson 2015

Reason for exclusion	Wrong intervention

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Alda 2011

[Empty]

Ang 2010

[Empty]

Castel 2009

[Empty]

Castel 2012

[Empty]

Edinger 2005

[Empty]

Falcao 2008

[Empty]

Haldorsen 1998

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Jensen 2012

[Empty]

Karlsson 2015

Karlsson B.; Burell G.; Anderberg U.M.; Svardsudd, K.. Cognitive behaviour therapy in women with fibromyalgia: A randomized clinical trial.. Scandinavian Journal of Pain 2015;9(Journal Article):11-21. [DOI: http://dx.doi.org/10.1016/j.sjpain.2015.04.027]

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Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

Classification pending references

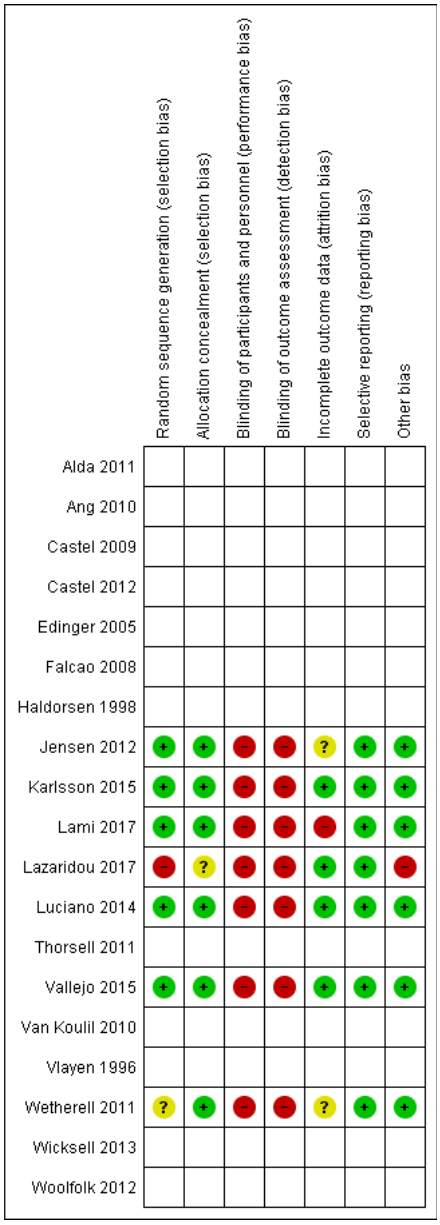
Data and analyses

1 Cognitive therapy vs treatment as usual/ waiting list uden subgrupper til MAGIC

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Pain EoT EoT	16	1012	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.51, -0.13]
1.3 Pain FU =< 6 m	12	793	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.56, -0.04]
1.5 Pain FU>6m	4	422	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.43, 0.01]
1.6 Function EoT	11	720	Std. Mean Difference (IV, Random, 95% CI)	-0.42 [-0.63, -0.20]
1.8 Function FU=<6 m	6	493	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.78, -0.22]
1.9 Function FU>6m	2	166	Std. Mean Difference (IV, Random, 95% CI)	-0.51 [-0.82, -0.20]
1.10 Quality of life (FIQ total)EoT	8	526	Mean Difference (IV, Random, 95% CI)	-6.38 [-13.42, 0.65]
1.12 Quality of life (FIQ total)FU =<6m	6	444	Mean Difference (IV, Random, 95% CI)	-8.69 [-15.93, -1.45]
1.15 Drop out all cause EoT	17	1163	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.84, 1.46]
1.16 Return to work FU>6m	1	469	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.82, 1.17]

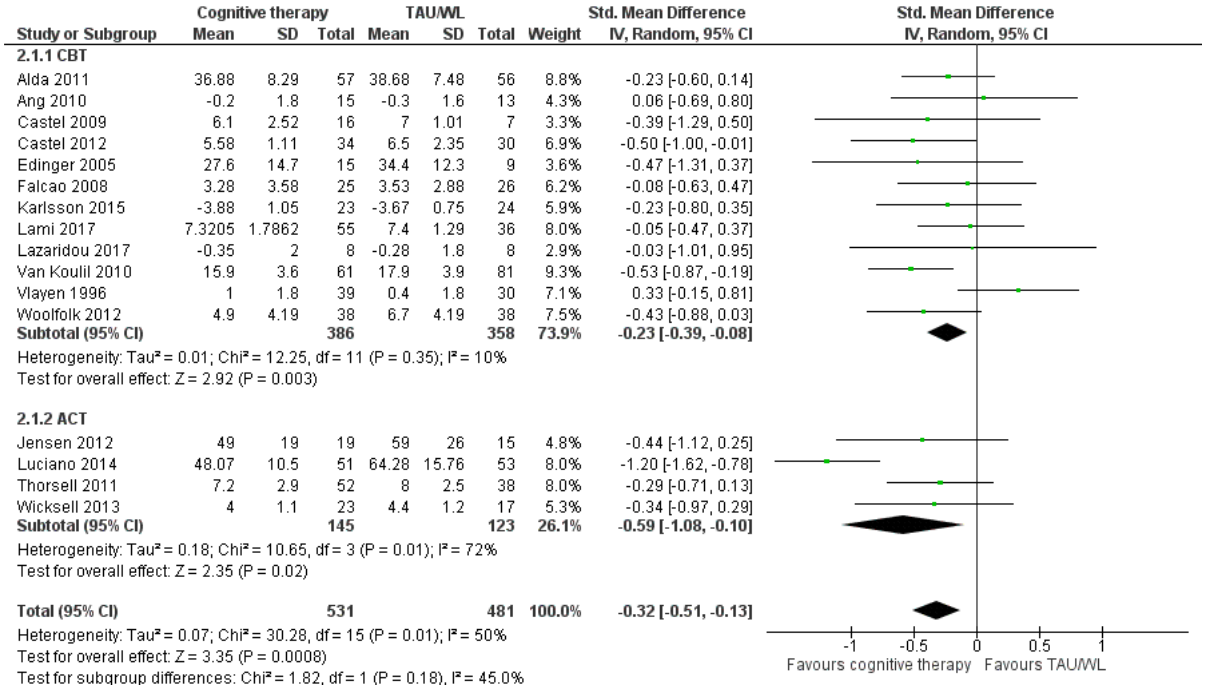
Figures

Figure 1



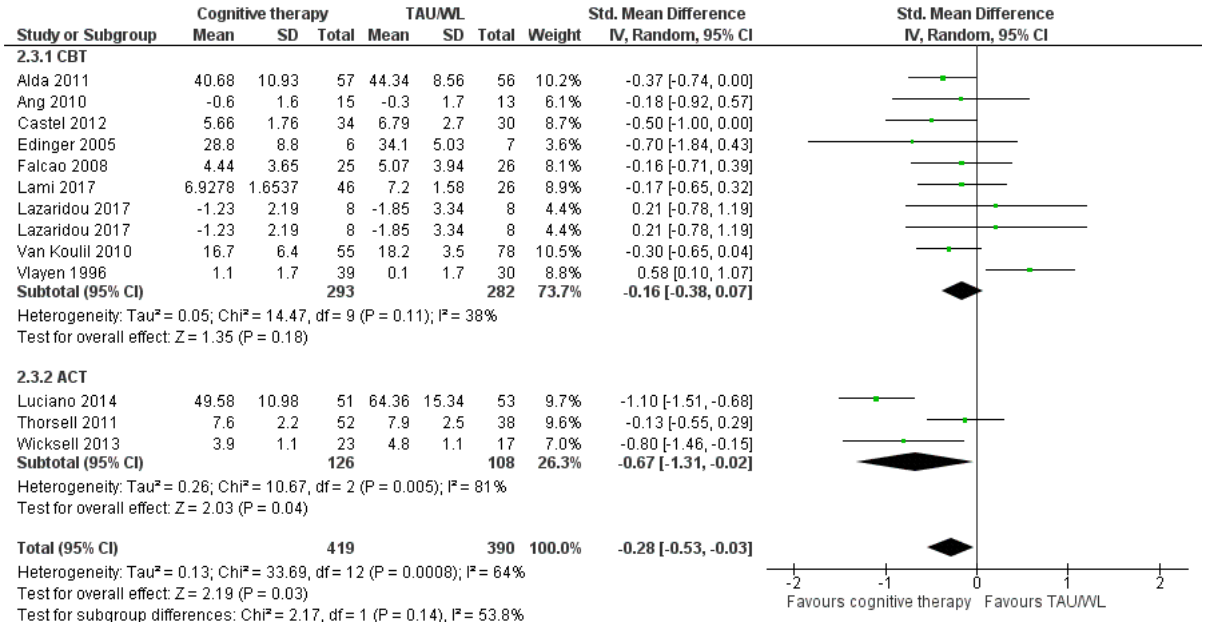
Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 2 (Analysis 2.1)



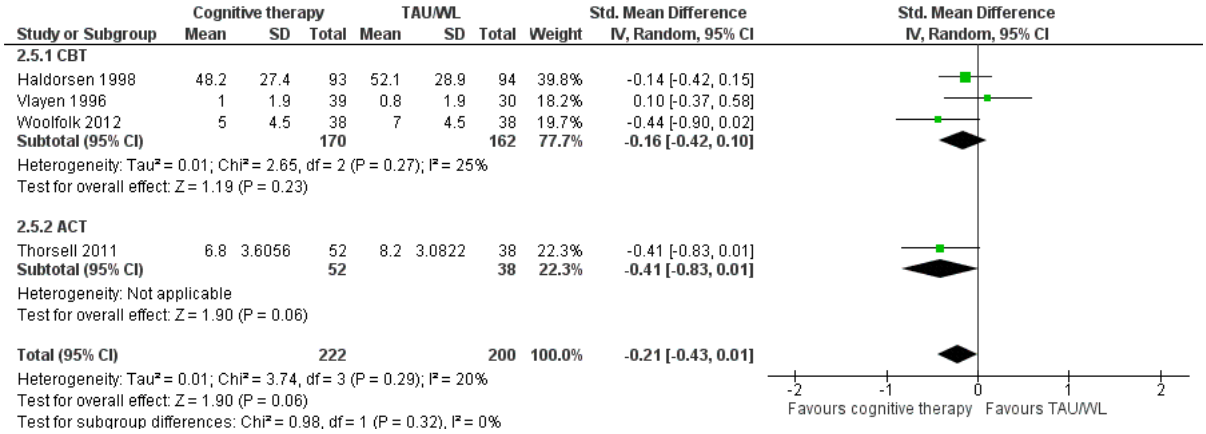
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.1 Pain EoT EoT.

Figure 3 (Analysis 2.3)



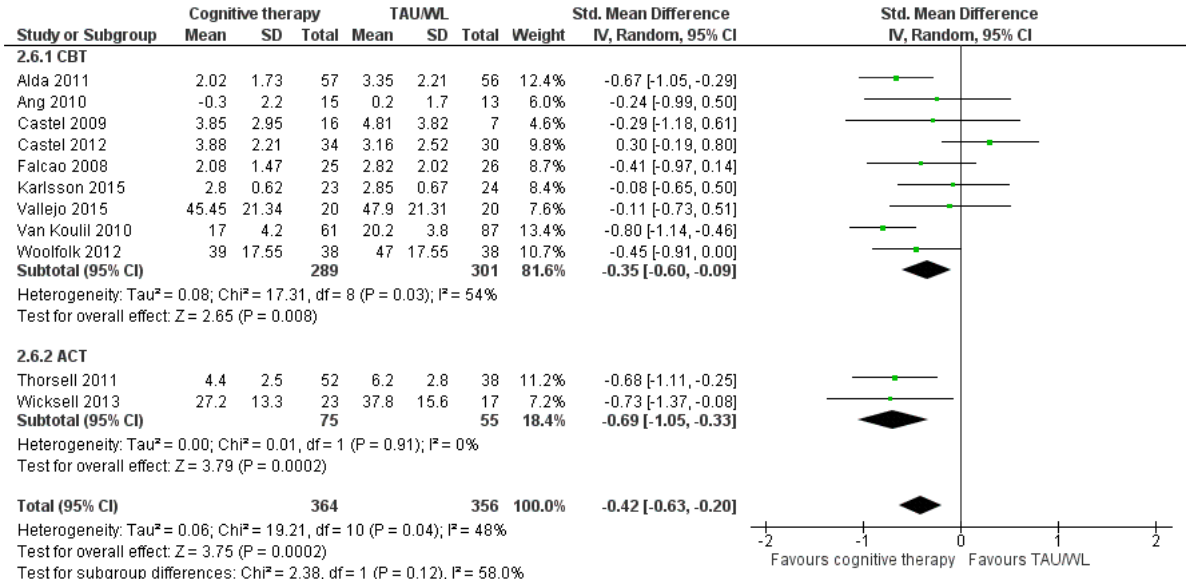
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.3 Pain FU =< 6 m.

Figure 5 (Analysis 2.5)



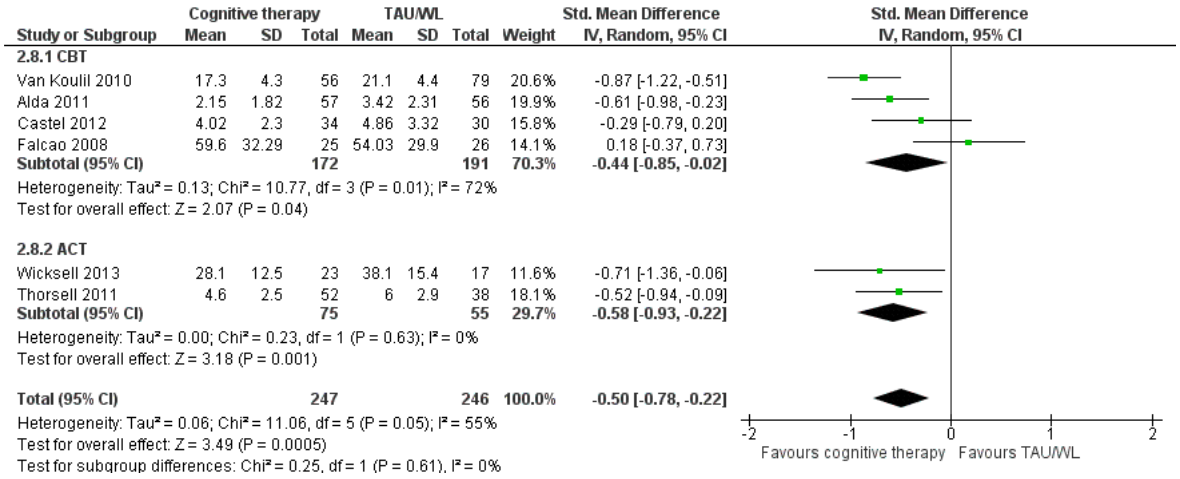
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.5 Pain FU>6m.

Figure 6 (Analysis 2.6)



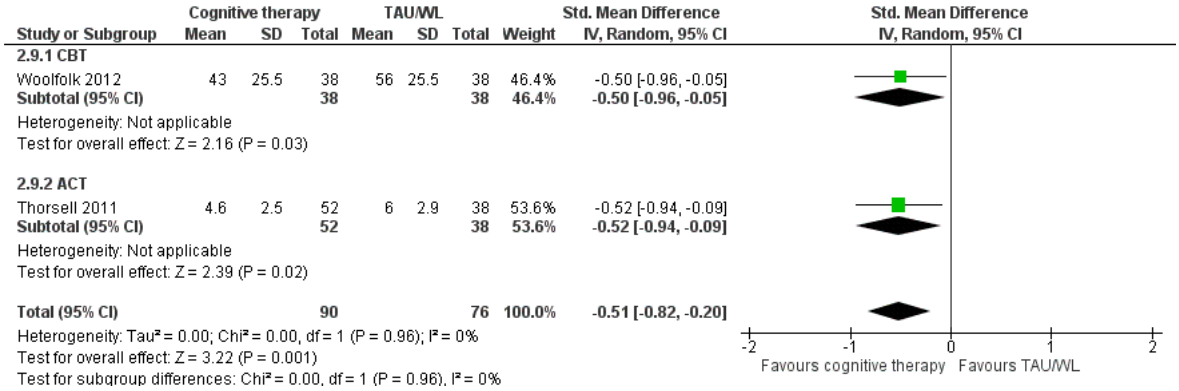
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.6 Function EoT.

Figure 8 (Analysis 2.8)



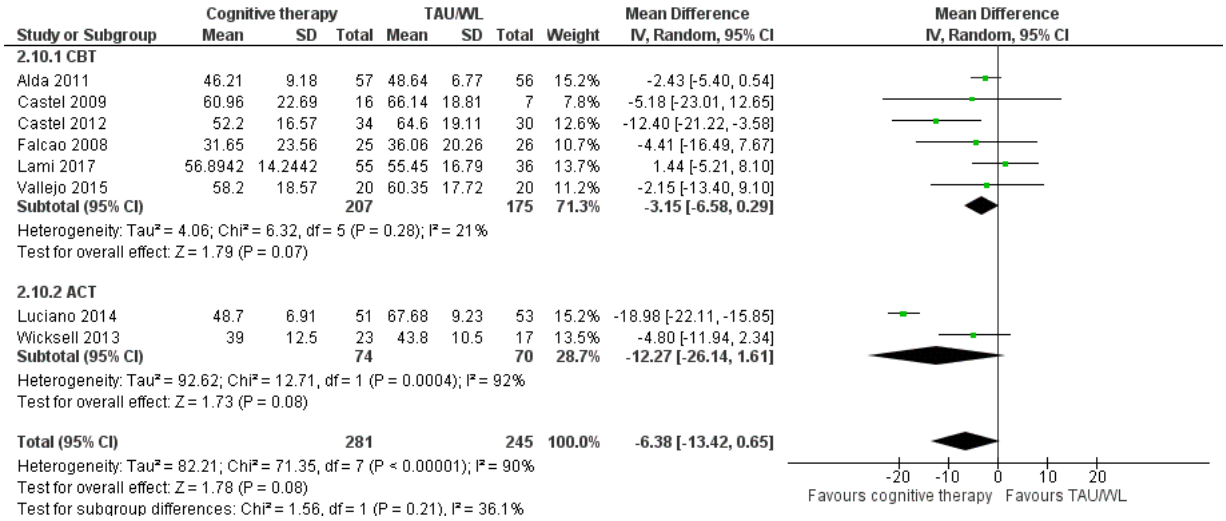
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.8 Function FU=<6 m.

Figure 9 (Analysis 2.9)



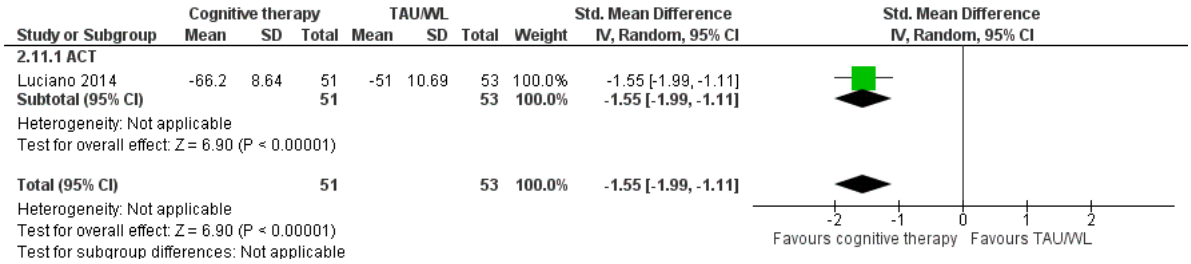
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.9 Function FU>6m.

Figure 10 (Analysis 2.10)



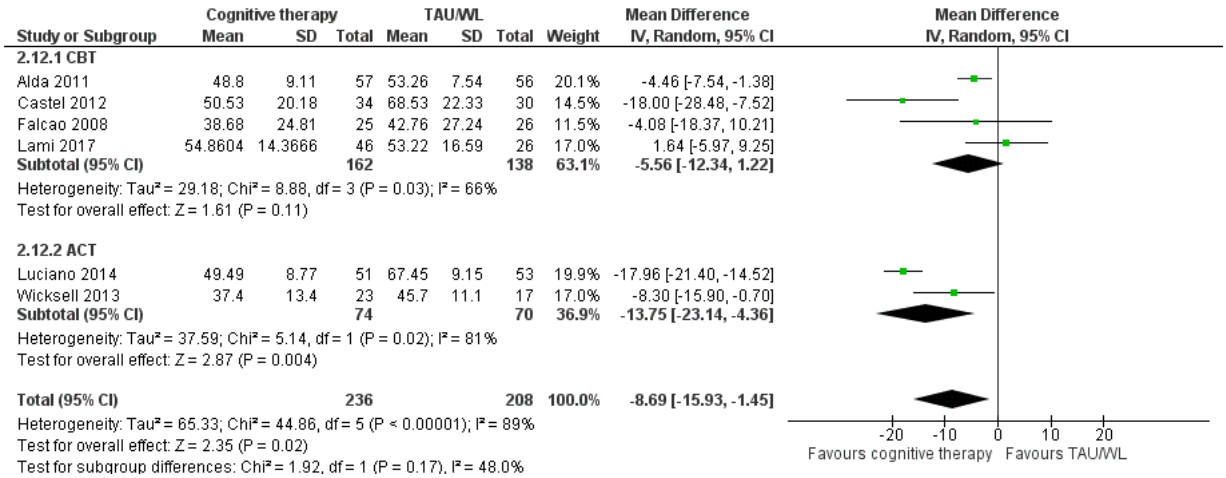
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.10 Quality of life (FIQ total)EoT.

Figure 11 (Analysis 2.11)



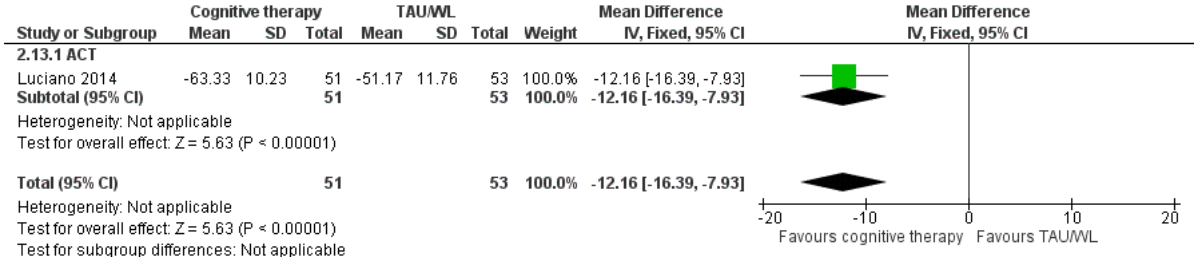
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.11 Quality of life (EuroQoL)EoT.

Figure 12 (Analysis 2.12)



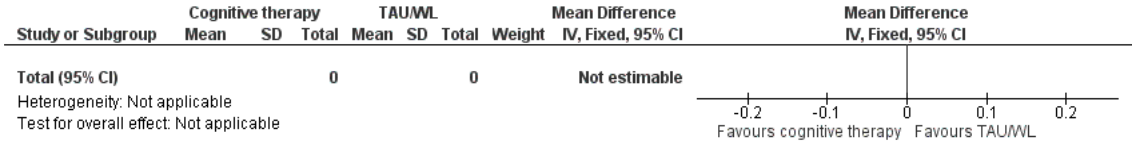
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.12 Quality of life (FIQ total)FU =<6m.

Figure 13 (Analysis 2.13)



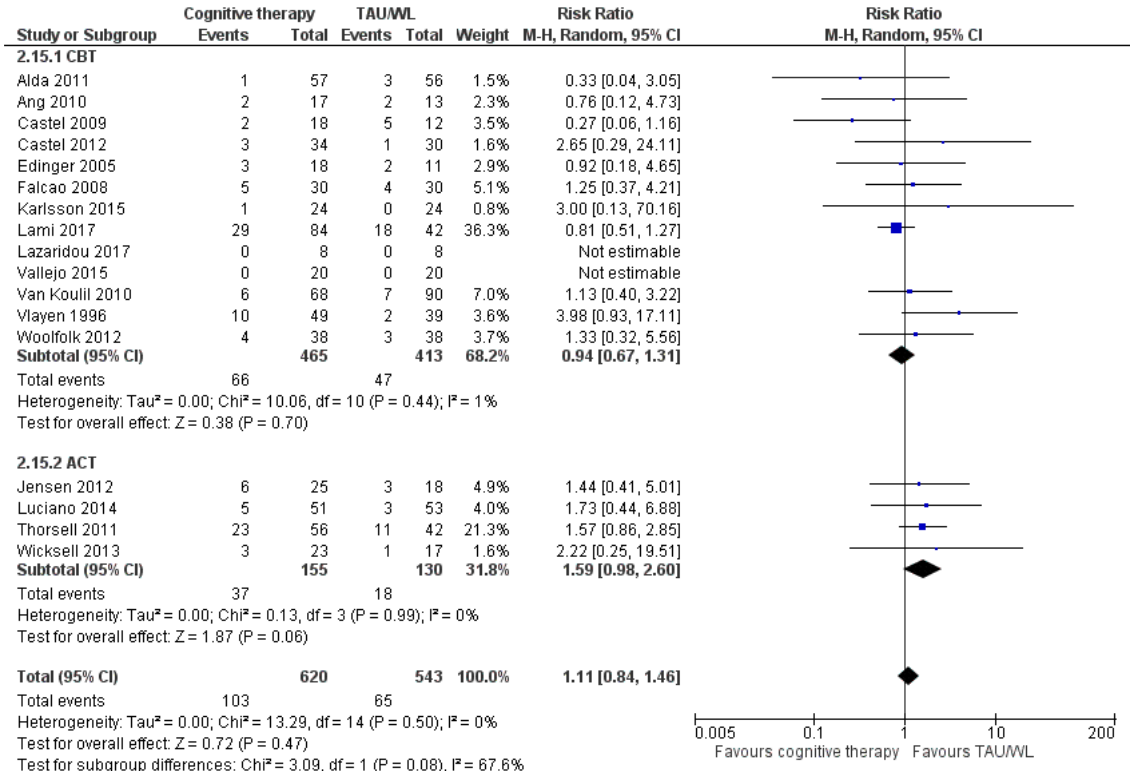
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.13 Quality of life (EuroqoL)FU =<6m.

Figure 14 (Analysis 2.14)



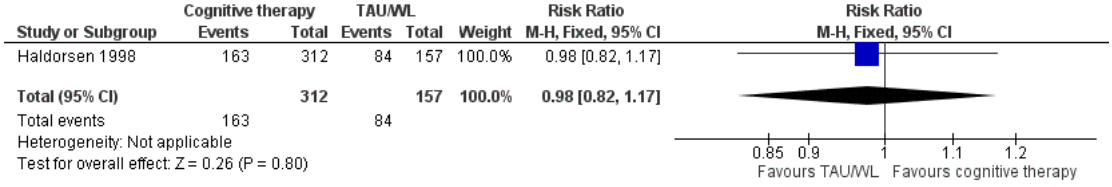
Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.14 Quality of life FU (EQ-5D)>6m.

Figure 15 (Analysis 2.15)



Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.15 Drop out all cause EoT.

Figure 16 (Analysis 2.16)



Forest plot of comparison: 2 Cognitive therapy vs treatment as usual/ waiting list, outcome: 2.16 Return to work FU>6m.