

What is the outcome for patients with fibromyalgia receiving cognitive-behavioural therapy?

### **Clinical bottom line**

There is mixed evidence to support the use of CBT in the management of FMS.

### **Population**

Male and female adults (18 years and over)

### **Intervention**

Cognitive-behavioural therapy (CBT)

### **Outcome**

Change in pain, functioning (disability).

### **Inclusions**

All CBT types  
Primary and Secondary Care

### **Exclusions**

Studies not in English

### **Databases included in search**

Cochrane, Pedro, NHS Library for Health, medline, Ahmed, Cinahl, Embase, PsycInfo, NICE guidelines, Bandolier, NELH, Professional websites (OTs, physios, psychologists, British Association of Counsellors and Psychotherapists), Guidelines.

Search: 1992-2007 (past 15 years).

### **Key words searched**

Fibromyalgia, cognitive-behavioural therapy (and all derivatives - cognitive behavioral therapy, cognitive behavioural therapy, cognitive behaviour therapy, cognitive behavior therapy, CBT). functional status, function, pain.

### **Types of studies**

Systematic reviews, RCT's, clinically controlled trials

### **Available evidence**

Database (specific to CAT)	Number of abstracts	Number of relevant abstracts
Cochrane	1	1
Pedro	7	4
NHS Lib for health	27	12

Medline		
Cinahl		
Embase		
PsycInfo		
NICE guidelines		
Bandolier	1	1
NELH	1	1
Professional web sites	1	
Web of Science		
Science Citation Index		
Total	38	19

## **Results**

### **Goldenberg DL, Burckhardt C, Crofford L (2004) Management of fibromyalgia syndrome**

Review carried out between 1966-2004. A total of 505 articles were reviewed. Review included all RCTs and meta-analyses of RCTs.

The objective of the review was to provide up-to-date evidence-based guidelines for the optimal treatment of FMS. It included pharmacological and non-pharmacological approaches. Literature review was performed by an interdisciplinary panel composed of 13 experts in various pain management disciplines.

Key finding: The data synthesis found major limitations to the FMS literature with treatment trials compromised by short duration and lack of masking.

Conclusion: They concluded that based on current evidence, a stepwise program emphasizing education, certain medications, exercise, cognitive therapy, or all four should be recommended.

### **Neilson WR and Jensen MP (2004) Relationship between changes in coping and treatment outcome in patients with Fibromyalgia Syndrome**

Aim: To examine the relationship between treatment process variables (pain related beliefs, coping strategies and treatment outcome in a sample of patients involved in a multidisciplinary treatment program for FMS. The study sample was 198 individuals with fibromyalgia using the ACR criteria.

Program: 4 weeks, 5 days per week outpatient FMS treatment program aimed at improving patient pain management skills and physical and psychological functioning. Assessed pre, post, and three and six months follow up.

Results showed increased sense of personal control over pain, a belief that one is not necessarily disabled by FM, a belief that pain is not necessarily a sign of damage, decreased guarding, increased use of exercise, seeking support from others, activity pacing and use of coping self statements.

Key finding: Support for an association between changes in beliefs and coping and changes in outcome following multidisciplinary pain treatment. .

Conclusion: The findings were consistent with a cognitive-behavioural model of fibromyalgia.

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### **Bradley LA, McKendree-Smith NE and Cianfrini LR (2003) Cognitive-behavioural therapy interventions for pain associated with chronic illnesses**

Review of studies of CBT in chronic conditions including FMS. Use American Psychological Association criteria for validating treatments to evaluate the CBT interventions.

Key findings: Most studies do not include an appropriate attention-placebo control. Uncontrolled investigations generally show CBT interventions to produce statistically or clinically significant reductions in patients' ratings of pain and other clinical symptoms, as well as functional disability. Some studies report that improvements in ratings of pain or functional ability were maintained for up to 30 months after treatment termination.

They looked at three studies that compared the outcomes of CBT, relative to credible attention-placebo conditions – Buckelew et al, 1998, Nicassio et al, 2000 and Vlaeyen et al, 1996. Nicassio and Vlaeyen found that CBT was no more effective than attention-placebo. Buckelew compared the effects of CBT to an exercise intervention, a combination of CBT and exercise, and the attention placebo condition. It was found that all three active treatments produced significantly better tender-point index scores than the attention-placebo. There was no significant CBT treatment effects on measures of pain or pain behaviour.

Conclusion: They concluded that at present CBT interventions cannot be considered superior to placebo and must be considered as experimental therapies for patients with FM.

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### **Thieme K, Flor H and DC Turk (2006) Psychological pain treatment in fibromyalgia syndrome: efficacy of operant behavioural and cognitive behavioural treatments**

Study focuses on the evaluation of the effects of operant behavioural treatment (OBT) and cognitive behavioural treatment (CBT) for FMS. 125

patients with ACR criteria for FMS were randomly assigned to OBT (n=43, CBT (n=42) or an attention-placebo treatment (n=40) .

Key findings: Methodological considerations - low sample sizes, no power calculation to make informed decision about this. Little information given about treatment packages, especially CBT package. All female patients.

Patients receiving the OBT or CBT reported a significant reduction in pain intensity post-treatment. In addition the CBT group reported statistically significant improvements in cognitive and affective variables. The OBT group also showed statistically significant improvements in physical functioning and behavioural variables. The AP group showed no significant improvement and actually deteriorated. The post-treatment effects for the OBT and CBT groups were maintained at both 6 and 12 month follow-up.

Conclusion: OBT and CBT are capable of producing both statistically significant and clinically meaningful benefits for patients with long-standing FMS. Changes maintained up to 12 months after treatment.

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**Rossy LA, Buckelew SP, Dorr N, Hagglund KJ, Thayer JF, McIntosh MJ, Hewett JE, Johnson JC (1999) A meta-analysis of fibromyalgia treatment interventions**

Meta-analysis of 49 FM treatment outcome studies carried out between 1966 and 1996 to assess the efficacy of pharmacological and non-pharmacological treatment (n=17) across four types of outcome measures, physical status, self-report of FMS symptoms, psychological status and daily functioning. Non-pharmacological treatment interventions were physically based, psychologically-based and combinations of the two. No further details were given about the interventions. Some of the studies had very low numbers, and from the brief description of the intervention were not CBT.

Key finding: All non-pharmacological treatments were associated with significant improvements in all four categories of outcome with the exception that physically based treatments did not significantly improve daily function.

Conclusion: The optimal intervention for FMS would include non-pharmacological treatments, specifically exercise and cognitive-behavioural therapy, in addition to appropriate medication management as needed for sleep and pain.

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**Sim J and Adams N (2002) Systematic review of randomized controlled trials of nonpharmacological interventions for fibromyalgia**

This review was carried out from 1980-2000 and yielded 25 RCTs. Five studies mention using cognitive behavioural approaches as part of other strategies i.e. relaxation, stress management, education, group therapy.

Key finding: It was difficult to establish the effectiveness of cognitive-behavioural approaches alone.

Conclusion: This review suggests that fibromyalgia is best managed by a multimodal approach.

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**Williams DA, Cary MA, Groner KH, Chaplin W, Glazer LJ, Rodriguez Am, and Clauw DJ (2002) Improving physical functional status in patients with fibromyalgia: a brief cognitive behavioural intervention**

RCT of 145 patients receiving: (1) standard medical care that included pharmacological management and suggestions for aerobic fitness, or (2) the same standard medical treatment plus 6 sessions of CBT. Outcomes were physical function and pain at baseline and at twelve months.

Key finding: Significant improvement in physical functioning in CBT group, no differences in pain between the groups at twelve months.

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**Burckhardt CS (2006) Multidisciplinary Approaches for Management of fibromyalgia**

Review of 17 studies (8 RCTs, 2 CT's and 7 uncontrolled single group). 8 studies mentioned using CBT (2 RCTs and 5 uncontrolled single group). CBT was used as part of multi-component strategies by multidisciplinary teams.

Key finding: Unable to establish effectiveness of CBT alone.

Conclusion: This review concluded that the evidence for advocating a multidisciplinary approach to FMS treatment is considered moderate to strong.

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**Nicassio PM, Radojevic V, Weisman MH, Schuman C, Kim J, Schoenfeld-Smith K, Krall T (1997) A comparison of behavioural and educational interventions for fibromyalgia**

Aim: To compare a behavioural intervention with an educational/control condition. The effects were evaluated across a 10-week treatment period and at six months.

Key finding: Improvement across time was found in depression, self-reported pain behaviours, observed pain behaviours and myalgia scores. No differences in these variables were found between the conditions.

Conclusion: The findings illustrate the value of psycho-educational interventions in decreasing the psychological and behaviour effects of FM.

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**Karjalainen K, Malmivaara A, van Tulder M, Roine R, Jauhiainen M, Nurri H, Koes B (2007) Multidisciplinary rehabilitation for fibromyalgia and musculoskeletal pain in working age adults**

Cochrane Review. Seven studies (RCTs) involving 1050 patients met inclusion criteria. All studies were of low methodological quality.

Conclusion: No evidence of efficacy was observed. However, behavioural treatment and stress management appear to be important components. Education combined with physical training showed some positive effects in long-term follow-up.

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**Mooney Y (2001) A Literature Review: What is the Evidence for the Value of a Cognitive Behavioural Programme as a Way of Managing Pain, Improving Coping Skills and Increasing Functionality for Individuals Diagnosed with Fibromyalgia**

Aim: To determine what the evidence is for a cognitive behavioural approach when treating fibromyalgia.

Key findings: Review of the literature – CBT is effective in decreasing pain severity, increasing control over pain and decreasing perceived interference with daily life and increasing function. There are, however, a number of limitations, including small convenient samples, lack of appropriate control groups, and failure to assess long-term outcomes.

Conclusions: Further study is required using large randomly selected samples, and to assess: (1) The potential effectiveness of a CBT approach embedded in a more comprehensive programme, including individual counselling, spouse involvement, and interventions aimed at fear reduction. (2) Function as a primary outcome measure. (3) Comparison of the effectiveness of CBT in in-patient and out-patient settings. (4) Studies that incorporate CBT techniques with a multidisciplinary team approach.

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**Vlaeyen JW, Teeken-Gruben NJ, Goossens ME, Rutten-van Molken MP, Pelt RA, van Eek H, Heuts PH (1996) Cognitive-educational treatment of fibromyalgia: a randomized clinical trial**

Aim: To evaluate the effectiveness of a 12-session outpatient cognitive/educational treatment group for patients with fibromyalgia. Patients were randomly assigned to 3 conditions: combined cognitive/educational intervention (ECO); an attention control condition consisting of group education plus group discussion (EDI) and: a waiting list control (WLC).

Key finding: The EDI patient improved on pain coping and pain control. They also reported less fear than ECO patients. However, based on reliability of

change index for clinical significance, the relative short-term success rates are 6.4 and 18.4% for ECO and EDI respectively.

Conclusion: A 12-session group cognitive treatment added to group education cannot be supported.

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**Oliver K, Cronan TA and Walen HR (2001) A Review of Multidisciplinary Interventions for Fibromyalgia Patients: Where Do We Go from Here?**

Aim: To review multidisciplinary treatment programs designed for people with fibromyalgia.

Key findings: Most efficacious interventions include physical activity and CBT. The authors recommend that future research needs to be carried and should include the following: (a) The use of aerobic exercise and CBT training in coping skills and relaxation. (b) Individualised exercise training. (c) Power analysis should be conducted a priori to determine appropriate sample size. (d) There should be uniformity in outcome measurement and follow-up assessment. (e) RCT would lead to stronger conclusions about treatment efficacy. (f) Follow up should continue for at least one year following the intervention.

Conclusion: Multidisciplinary treatment programs for fibromyalgia are generally effective. Future research should take into consideration the points made above.

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**Yousefi P and Coffey J (2005) For fibromyalgia, which treatments are the most effective?**

Review.

Conclusion: CBT and CBT combined with education and exercise has been found to be effective. Some evidence suggests that acupuncture, massage, warm baths, and biofeedback are effective.

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**Williams DA (2003) Psychological and behavioural therapies in fibromyalgia and related syndromes**

Review. Definition of CBT varies with each study. Studies compare CBT as part of a combination of treatment, rather than individually.

Conclusion: Some support for CBT in fibromyalgia, but further investigation required. CBT is better when combined with exercise

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**Soares JFJ and Grossi G (2002) A randomised Controlled comparison of education and behavioural interventions for women with fibromyalgia**

Aim: To compare an educational intervention (2 x 2 hour individual sessions and 15 x 2 hour group sessions) delivered by a physiotherapist and 'others' with behavioural intervention (5 x 1 hour individual sessions and 15 x 2 hour group sessions) delivered by a psychologist in a Swedish female population (n=53). Waiting list control.

Key findings: Educational intervention did not lead to any changes. Behavioural intervention improved coping, functional disability, pain perception, quality of sleep, and some aspects of self-efficacy. Only quality of sleep maintained at 4 months. The waiting list control deteriorated in coping and pain.

Conclusion: Education alone is of limited or inconclusive clinical value.

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**Redondo JR, Justo CM, Moraldea FV, Velayos YG, Puc he JJ, Zubero JR, Hernandez TG, Ortells LC, Pareja MA (2004) Long-term efficacy of therapy in patients with fibromyalgia: a physical exercise-based program and a cognitive-behavioral approach**

Aim: Comparing CBT (once per week for 2.5 hours x 8 weeks) and physical exercise (45 minutes x 5 per week x 8 weeks). No control group. Follow-up 12 months. Female population (n=40).

Key findings: Physical exercise group showed improved functional capacity. CBT – physical activity of vertebral column improved. No differences reported in anxiety, depression and self-efficacy in either group. At one-year follow-up most parameters had returned to baseline, except functional capacity in the physical exercise group, which remained significantly better.

Conclusion: Both CBT and exercise have short-term benefits.

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**Morley S, Eccleston C, Williams A (1999) A systematic review and meta-analysis of randomised controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache**

25 studies reviewed – 19 randomised controlled trials, 6 non-randomised. Various populations: chronic low back pain, rheumatoid arthritis, osteoarthritis, mixed back pain, fibromyalgia, upper limb pain and unspecified pain. Interventions included: CBT, behaviour therapy or biofeedback.

Conclusion: Diverse studies showed that CBT is effective in reducing the pain experience and improving positive behaviour expression, appraisal and coping in individuals with chronic pain.

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## **Kurtais Y, Kutlay S and Ergin S (2006) Exercise and cognitive behavioural treatment in fibromyalgia syndrome**

Systematic review.

Conclusion: Inconclusive results about efficacy of CBT due to the limited number of studies and small sample sizes. Overall, however, the results of trials demonstrate the beneficial effects of exercise and CBT, and suggest that combined exercise and CBT may have significant long-term effects.

This is not a systematic review. There is no information on the search strategy. Majority of articles focus on exercise.

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### **Overall conclusions**

Studies to date are limited by methodological issues. Many of the studies lack a definition of FMS, and CBT is often poorly defined and often delivered in conjunction with other approaches. Studies do not state the level of training the clinician has in relation to CBT, nor do they monitor delivery of CBT approach. The sample sizes in some instances are small and no power calculations reported. Follow-up is often up to 6 months.

### **Implications for practice**

From the papers reviewed there is mixed evidence to support the use of CBT in the management of FMS.

### **Further research question**

A well designed research study is needed which addresses the above issues, including clinical definition of fibromyalgia and CBT. Adequate sample size, and monitoring of delivery of CBT intervention. Clinicians should have received specific CBT training, and their level of training and the intervention delivered should be clearly defined.

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