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Cognitive–behavioural therapies and exercise programmes for patients with fibromyalgia: state of the art and future directions

S van Koulil, M Efftig, F W Kraaimaat, W van Lankveld, T van Helmond, H Cats, P L C M van Riel, A J L de Jong, J F Haverman, A W M Evers

This review provides an overview of the effects of non-pharmacological treatments for patients with fibromyalgia (FM), including cognitive–behavioural therapy, exercise training programmes, or a combination of the two. After summarising and discussing preliminary evidence of the rationale of non-pharmacological treatment in patients with FM, we reviewed randomised, controlled trials for possible predictors of the success of treatment such as patient and treatment characteristics. In spite of support for their suitability in FM, the effects of non-pharmacological interventions are limited and positive outcomes largely disappear in the long term. However, within the various populations with FM, treatment outcomes showed considerable individual variations. In particular, specific subgroups of patients characterised by relatively high levels of psychological distress seem to benefit most from non-pharmacological interventions. Preliminary evidence of retrospective treatment analyses suggests that the efficacy may be enhanced by offering tailored treatment approaches at an early stage to patients who are at risk of developing chronic physical and psychological impairments.

Fibromyalgia (FM) is a chronic musculoskeletal pain syndrome characterised by widespread pain and tenderness in at least 11 of the 18 so-called tender points. Patients frequently report sensations of fatigue, sleep disturbances, morning stiffness, symptoms associated with irritable bowel syndrome and affective distress. The prevalence of FM in Western countries varies between 2% and 10% and the majority of the patients is female. Most patients report a high degree of impairment in their daily functioning. In comparison with other chronic pain conditions, patients with FM report higher levels of pain and functional disability and judge their quality of life as poorer. Moreover, they make extensive use of health services, thus leading to high costs for medical and societal care. The syndrome’s pathology is not well understood, and to date no treatment has proven effective in fully alleviating its symptoms.

Over the past few decades, a wide range of potential treatments has been applied and evaluated. Pharmacological therapies primarily comprise analgesics, antidepressants, anticonvulsants, hormone therapy or a combination of these drugs. A recent review of the various treatments showed that tricyclic antidepressants—for example, amitriptyline and cyclobenzaprine—are the most promising in reducing pain and sleep problems in patients with FM. However, it has been argued that many patients report symptoms of drug intolerance and consequently discontinue taking them. Furthermore, the treatment effects disappear as soon as the treatment regimen is ended. Medication mainly focuses on short-term relief of symptoms, whereas non-pharmacological interventions aim to address the long-term consequences of the disease, such as disability, psychological distress, muscular deconditioning and weakness. Interventions mainly consist of elements of cognitive–behavioural therapy (CBT), exercise training, or a combination of the two. Overall, reviews have shown non-pharmacological approaches to be more effective than pharmacological treatments. Several meta-analyses have specifically examined the effects of non-pharmacological interventions for patients with FM. It is concluded that the combination of CBT and exercise training is the most effective treatment. Non-pharmacological interventions such as CBT and exercise programmes are generally based on biopsychosocial models of FM and chronic pain.

Rationale of CBT and exercise programmes

Biopsychosocial models describe the transition of acute to chronic pain, independent of a biomedical cause, as in FM. In acute pain, three response systems are involved: behavioural reactions (eg, avoidance behaviour), cognitive reactions (eg, increased attention to bodily sensations and catastrophising) and physiological reactions (eg, an elevated autonomous arousal and muscle tension). All are appropriate adaptive short-term reactions to acute pain, but they become less functional and even detrimental when applied long term and in response to chronic pain.

Avoidance behaviour has been described as an important aspect contributing to the aggravation of pain. This behaviour is affected by classic and operant learning processes, and is an prominent factor of the fear–avoidance model. The key concept of the model is fear of pain following the
sensation of acute pain—for example, pain experienced during or after a road accident. People may react to this pain-related fear with avoidance or withdrawal of activities in order to prevent or escape pain. Cognitions such as the expectation that an activity will lead to pain or an increase in pain may also trigger avoidance behaviour. Avoidance behaviour is easily reinforced by the belief that one has successfully prevented increments in pain. As long as activities are avoided, it is impossible to refute the belief that activity will lead to pain. Catastrophising is another important cognitive factor that plays a role in chronic pain. People who have exaggerated negative interpretations of pain show elevated levels of pain-related distress and maintain avoidance behaviour. In addition, avoidance may intensify attention to bodily sensations, triggering hypervigilance to pain. Long-lasting avoidance of activities can lead to changes in the musculoskeletal system caused by physical deconditioning and impairments in muscle coordination, also called the disuse syndrome. The resultant deficient physical condition may in turn exacerbate the pain problem. Physiological reactions to pain such as heightened muscular tension and increased autonomic arousal may also lead to higher levels of pain and functional disability in the long term. Furthermore, this autonomic arousal could be misinterpreted as evidence of physical harm and subsequently lead to more avoidance behaviour. This habitual pattern of physiological, behavioural and cognitive reactions to pain might be generalised to various other situations and areas independent of objective pathology and intensity of pain. Patients with high levels of avoidance behaviour have been shown to have a tendency to restrict their daily and social activities and withdraw from work, which will negatively affect long-term pain outcomes. Social factors, such as external reinforcements from the patient’s social network, can further reinforce and maintain avoidance behaviour. In addition, avoidance may also give rise to negative reinforcements such as leisure activities which in turn exacerbate psychological distress and reduce their quality of life. A vicious cycle has thus been established.

There has been incidental evidence from experimental and prospective studies for the various factors of biopsychosocial models in FM. For example, higher levels of pain and depression and a lower quality of life in FM could be prospectively predicted by catastrophising. Experimental studies have shown that patients with FM tend to display hypervigilance for aversive stimuli such as pain or for bodily sensations in general. Furthermore, a large number of cross-sectional studies underline the relevance of cognitive behavioural factors in FM. Crombez and colleagues found that patients with FM reported higher vigilance to pain and more intense catastrophic fear of pain than other patients with chronic pain. Catastrophising has been found to be associated with higher levels of disability and pain. Finally, fear of pain is associated with an increased susceptibility to pain and greater disability and depressed mood in patients with FM. Studies on mediators of change in CBT treatment of patients with FM and chronic pain also provide evidence for possible mediating effects of specific cognitive behavioural factors. For example, several studies have shown that reductions in catastrophising and helplessness are related to and partly mediate CBT treatment outcomes of, for example, disability and depression in chronic pain. Although these findings are by no means conclusive and clearly warrant additional longitudinal and experimental research, these results deliver a preliminary theoretical basis that non-pharmacological treatments consisting of CBT and exercise programmes can be beneficial for patients with FM.

Attempts have been made to direct non-pharmacological treatments to these cognitive behavioural factors. Treatments that include exposure or graded activity elements, for instance, aim at changing the patient’s pain experience and disability by challenging their avoidance behaviour through disproving the cognition that activity will lead to pain or an increment of pain. Furthermore, interventions have focused on curbing the negative interpretation of pain by challenging catastrophic cognitions through cognitive restructuring. Another approach suggests that involving a support person from the patient’s social network in the intervention could help the patient to deal with reinforcements of their pain behaviour that they receive from their social networks and facilitate the implementation of coping skills. Exercise training exploits muscle-strengthening and aerobic exercises in order to break the deconditioning cycle. Most studies on non-pharmacological interventions in FM include one or more of the aforementioned therapeutic elements. However, a major problem in the treatment of patients with FM is that most of the non-pharmacological treatments are thus far not systematically based on this rationale. In general studies include a broad range of unspecified CBT techniques that are not directly focused on specific dysfunctional cognitive behavioural mechanisms for patients with FM.

**Purpose of this study**

Meta-analyses have shown that the effects of non-pharmacological interventions for patients with FM are, in general, limited and there appears to be a high individual response variation. This underlines the need for a better understanding of the factors that predict and enhance the efficacy of the treatment for FM. To evaluate the merit of CBT and exercise training in FM and to identify patient and treatment characteristics that might contribute to an optimisation of treatment outcome, various strategies have been adopted. Experimental and prospective studies have been conducted to find empirical evidence for the theoretical rationale for CBT and exercise in FM. Other designs have evaluated the effectiveness of randomised, controlled trials of CBT and exercise in FM, and yet others have tried to identify factors that help predict the success of treatment. In this review, we provide an overview of empirical studies of non-pharmacological treatment in patients with FM. The effects of CBT and exercise training targeting patients with FM are described for the main outcomes of pain, disability and mood. Furthermore, we have screened the studies included in our review for specific treatment or patient characteristics that may enhance the efficacy of the treatment. We elaborate on this issue by proposing and discussing other potentially promising aspects of future non-pharmacological FM interventions based on recent developments in other populations with chronic pain, and provide recommendations for future research.

**METHODS**

The electronic bibliographic databases we used in our search for relevant studies for the review included MEDLINE (1966–January 2006), PsychINFO (1806–January 2006), EMBASE (1980–January 2006) and Cochrane Library (1993–January 2006). The keyword “fibromyalgia” was used in combination with the terms “randomised”, “controlled”, “clinical trial”, “randomised controlled trial”, “cognitive therapy”, “CBT” and “exercise”. In addition, reference sections and review papers on non-pharmacological treatments of FM were screened manually. To be included in our review, the following criteria were needed to be met: (1) evaluation of non-pharmacological interventions for patients with FM founded on recognised diagnostic criteria; (2) intervention contains cognitive or activity elements of CBT and/or exercise programmes; (3) a randomised, controlled study design with a control group that received no treatment, a standard default treatment or an unspecified CBT techniques that are not directly focused on specific dysfunctional cognitive behavioural mechanisms for patients with FM.
intervention that was not expected to yield clinically relevant effects (eg, non-specific treatment group/placebo control group); and (4) effect analyses of interaction effects or separate t-tests based on the three outcome measures—namely, pain, disability and mood. If a research group published more than one article evaluating the same intervention, the most recent publication was included in the review. In all, 30 studies met the inclusion criteria (table 1†+), and their findings were evaluated by reviewing the short-term and long-term effects on the three specified outcome measures. The factor pain was assessed by means of various instruments, including visual analogue scales (VAS), myalgic scores, tender points and subscales of questionnaires (eg, the Fibromyalgia Impact Questionnaire (FIQ) and the Multidimensional Pain Inventory (MPI)). Disability was determined using tests of physical fitness (eg, 6 min walk, perceived exertion, flexibility test) and subscales of questionnaires such as the FIQ physical function scale and the physical activity scale of the Arthritis Impact Measurement Scales (AIMS). Finally, assessment of the outcome variable mood included VAS, questionnaires for psychological distress in general, such as the Beck Depression Inventory and the Symptom Checklist-90-Revised, and subscales of questionnaires for FM and other chronic pain conditions (eg, FIQ depression and anxiety scale, AIMS depression and anxiety scales, MPI affective distress scale).

RESULTS

Effects of CBT and exercise programmes

To find empirical support for non-pharmacological treatments for patients with FM, studies have examined the efficacy of specific therapeutic approaches such as CBT and exercise training programmes, as well as combinations of the two approaches. The findings of the randomised controlled trials our search generated are reviewed below.

Cognitive–behavioural therapy

CBT is one of the most prevalent treatments for patients with FM. A distinction can be made between single-method interventions such as education and relaxation programmes, and multimethod CBTs that incorporate various methods and skills from cognitive-behavioural approaches.

Educational programmes provide information about active self-management of pain, coping, relaxation techniques, the importance of physical activity and social support, and individual strategies for behavioural change. Three studies investigated the effect of education as a single-method intervention and found the educational programmes to yield some benefits for the patients’ self-efficacy and pain-coping skills. However, the programmes were not effective in diminishing pain and disability nor in improving mood. The only study that conducted a follow-up failed to find any treatment effect. Other single-method CBTs are relaxation techniques—for example, progressive relaxation, biofeedback and autogenic training—which are used in patients with FM to diminish muscular tension and interrupt the pain–tension cycle. The three studies that investigated the effects of relaxation failed to find any results for disability or mood; two studies reported improvements on pain; although the effect had not been maintained at follow-up. However, the study of Ferraccioli et al. may have been underpowered to detect effects due to its small sample size.

Multimethod CBT typically consists of a combination of various therapeutic elements, such as cognitive restructuring, pain-coping skills, problem-solving techniques, goal setting, increasing activity levels, activity pacing, stress management and adjustment of pain-related medication, and frequently also comprises educational and relaxation components. Five studies evaluated the outcome of multimethod CBTs. Two studies found no effects on pain, disability and mood, while three studies reported varying effects. Wiggers et al. reported the multimethod CBT to be initially effective in diminishing pain and depression, but this improvement was not sustained during the 4-year follow-up. Another CBT study aimed at improving physical functioning proved effective in reducing disability 1 year after treatment. Finally, Thieme et al. reported in their evaluation of a behavioural pain treatment for patients with FM that, compared with the control group, pain, disability and mood had all largely improved in the experimental group and the effects were maintained at the 15-month follow-up.

Exercise training

In the past few decades many studies on effects of exercise training programmes in patients with FM have been conducted. Exercise training programmes include aerobic exercise, strength training, flexibility exercises and hydrotherapy. Although the programmes vary, all have some of the following basic elements: a gradual build-up of strength and endurance, emphasis on the importance of frequent exercise and a moderately intense exercise programme. Because they facilitate the exercises and minimise post-exercise pain, pool exercises and hydrotherapy are occasionally part of the training programmes. Aerobic exercise is the most widely used exercise intervention and comprise various types of exercises such as cycling, walking and aerobic dancing. Ten studies investigated the effect of aerobic exercise, and six of these found improvements on disability, pain relief, and changes in mood; were rarely mentioned, and one study even reported an increase in disability. Only three studies conducted follow-up assessments of which one showed limited long-term improvements in pain and disability. Strength training has been investigated three times in randomised, controlled trials and positively affected disability in two of the three studies, although no effects on mood or pain were found. However, the study of Kingsley et al. could be biased, due to high dropout rates in the experimental group. Finally, five studies evaluated aerobic exercise in combination with muscle-strength training and obtained mixed results. Three studies demonstrated a decrease in pain and disability and these effects were maintained at follow-up. In addition, two studies reported a lesser worsening of disability levels in the intervention group compared with the control group.

Combinations of CBT and exercise training

Six studies examined the effectiveness of education in combination with exercise. Two reported effects on disability, such as an enhanced physical condition. Only in one study did patients also report an improvement in pain and mood. Of the three studies that included follow-up assessments, two studies found long-term effects on pain and disability; and one also on mood. The improvements on pain and disability in the study of Zijlstra and colleagues were only apparent at the 3-month follow-up and not at 6 and 12 months.

Relaxation combined with exercise training appeared to be effective in diminishing pain and disability in daily life, and the effects were maintained at the 1-year follow-up. However, in this study, pain alleviation was largely accounted for by a deterioration of the control group.

Although only two trials have been conducted with interventions that combined multimethod CBT and exercise training, the available findings look promising. Patients reported post-treatment improvements on pain, disability and mood and at the 3-month follow-up, they reported less pain.

Predictors of treatment outcome of CBT and exercise programmes

From this and previous reviews it appears that, overall, the effects of non-pharmacological interventions in patients with
<table>
<thead>
<tr>
<th>Author, year</th>
<th>n (completing), mean age (years), % women</th>
<th>Follow-up assessment</th>
<th>Control group, n (completing)</th>
<th>Intervention</th>
<th>Intervention group n (completing)</th>
<th>Outcome measures</th>
<th>Effects</th>
<th>Follow-up</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buckelew, 1998</td>
<td>119 (101), 440, 91</td>
<td>Post 3 mo 1 yr 2 yr</td>
<td>Education, 30 (27)</td>
<td>Relaxation (biofeedback) Individual and group; outpatient; 1x wk for 6 wk indiv and 1x mo for 2 yr group</td>
<td>29 (25)</td>
<td>Pain Disability Mood</td>
<td>0 0</td>
<td>0 0</td>
<td>Long-term effect of relaxation-exercise on pain was only evident at 3 mo, not at the 1-yr and 2-yr follow-ups</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Exercise training (aerobic and strength) Individual and group; outpatient; 1x wk for 6 wk indiv and 1x mo for 2 yr group</td>
<td>30 (26)</td>
<td>Pain Disability Mood</td>
<td>0 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Relaxation + exercise training Individual and group; outpatient; 1x wk for 6 wk indiv and 1x mo for 2 yr group</td>
<td>30 (27)</td>
<td>Pain Disability Mood</td>
<td>0 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burckhardt, 1994</td>
<td>99 (86), 46.5, 100</td>
<td>Post Waiting list 35 (30)</td>
<td>Education</td>
<td>Group; outpatient; 1x wk for 6 wk</td>
<td>31 (28)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>0 NA</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education + exercise training (aerobic) Group; outpatient; 1x wk for 6 wk</td>
<td>33 (28)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>0 NA</td>
<td></td>
</tr>
<tr>
<td>Cedraschi, 2004</td>
<td>164 (129), 49.3, 93</td>
<td>6 mo Waiting list 80 (68)</td>
<td>Education + exercise training (aerobic)</td>
<td>Group; outpatient; 2x wk for 6 wk</td>
<td>84 (61)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>15%</td>
<td>intervention 27.4%</td>
</tr>
<tr>
<td>Da Costa, 2005</td>
<td>80 (61), 50.8, 100</td>
<td>Post 3 mo 9 mo</td>
<td>Treatment as usual 41 (33)</td>
<td>Exercise training (aerobic, strength and flexibility) Individual; home-based; 12 wk and 4 sessions with physical therapist</td>
<td>39 (28)</td>
<td>Pain Disability Mood</td>
<td>0 0</td>
<td>19.5%</td>
<td>intervention 28.2%</td>
</tr>
<tr>
<td>Ferraccioli, 1987</td>
<td>12 (12), 57.0, 100</td>
<td>Post False biofeedback relaxation, 6 (6)</td>
<td>Relaxation (biofeedback) Group; outpatient; 2x wk, 15 sessions in total</td>
<td></td>
<td>6 (6)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>0 NA</td>
<td>No between-group analyses</td>
</tr>
<tr>
<td>Gowans, 1999</td>
<td>45 (41), 45.5, 78</td>
<td>Post Waiting list 22 (21)</td>
<td>Education + exercise training</td>
<td>Group; outpatient; 2x wk for 6 wk</td>
<td>23 (20)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>0 NA</td>
<td></td>
</tr>
<tr>
<td>Gowans, 2001</td>
<td>51 (31), 47.9, 90</td>
<td>Post Treatment as usual, 24 (16)</td>
<td>Exercise training (aerobic, pool exercises) Group; outpatient; 3x wk for 23 wk</td>
<td></td>
<td>27 (15)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>33.3%</td>
<td>intervention 44.4%</td>
</tr>
<tr>
<td>Jones, 2002</td>
<td>68 (56), 47.8, 100</td>
<td>Post Flexibility exercises, 34 (28)</td>
<td>Exercise training (strength) Group; outpatient; 2x wk for 12 wk</td>
<td></td>
<td>34 (28)</td>
<td>Pain Disability Mood</td>
<td>0 NA</td>
<td>0 NA</td>
<td></td>
</tr>
<tr>
<td>Keel et al, 1998</td>
<td>32 (27), 490, 89</td>
<td>Post Relaxation 16 (13)</td>
<td>CBT + exercise training (stretching and aerobic) Group; outpatient; 1x wk for 13 wk</td>
<td></td>
<td>16 (14)</td>
<td>Pain Disability Mood</td>
<td>0 0</td>
<td>0 0</td>
<td>(a) Positive post-treatment trend for pain, significant at follow-up; (b) predictor of treatment success: shorter disease duration</td>
</tr>
<tr>
<td>Author, year</td>
<td>n (completing), mean age (years), % women</td>
<td>Follow-up assessment</td>
<td>Control group, n (completing)</td>
<td>Intervention</td>
<td>Treatment characteristics: individual/group; inpatient/outpatient; duration</td>
<td>Intervention group n (completing)</td>
<td>Outcome measures</td>
<td>Effects</td>
<td>Comments</td>
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<tr>
<td>King, 2002</td>
<td>41 (95), 46.1, 100</td>
<td>Post 3 mo</td>
<td>Waiting list, 39 (18)</td>
<td>Education (1)</td>
<td>Group; outpatient; 1x wk for 12 wk</td>
<td>48 (21)</td>
<td>Pain</td>
<td>0</td>
<td>Dropout &gt;20%: Control 53.8%, intervention (1)</td>
</tr>
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<td></td>
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<td></td>
<td><strong>Exercise training (aerobic) (2)</strong></td>
<td>Group; outpatient; 3x wk for 12 wk</td>
<td>46 (30)</td>
<td>Pain</td>
<td>0</td>
</tr>
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<td></td>
<td></td>
<td><strong>Education + exercise training (aerobic) (3)</strong></td>
<td>Group; outpatient; 3x wk for 12 wk</td>
<td>37 (26)</td>
<td>Pain</td>
<td>0</td>
</tr>
<tr>
<td>Kingsley, 2005</td>
<td>29 (20), 46.0, 100</td>
<td>Post</td>
<td>Waiting list, 14 (12)</td>
<td>Exercise training (strength)</td>
<td>Group; outpatient; 2x wk for 12 wk</td>
<td>15 (8)</td>
<td>Pain</td>
<td>0</td>
<td>Dropout &gt;20%: control 14.3%, intervention</td>
</tr>
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<td></td>
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<td></td>
<td><strong>CBT + exercise training</strong></td>
<td>Group; outpatient; 24 sessions in 6 wk</td>
<td>43 (36)</td>
<td>Pain</td>
<td>+</td>
</tr>
<tr>
<td>Lemstra, 2005</td>
<td>79 (72), 49.4, 84.8</td>
<td>Post</td>
<td>Treatment as usual, 36 (36)</td>
<td>Education + exercise training (physical exercise)</td>
<td>Group; outpatient; education 1x mo for 6 mo; exercise 1x wk for 6 mo</td>
<td>37 (28)</td>
<td>Pain</td>
<td>+</td>
<td>NA</td>
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<td><strong>Mannerkorpi, 2000</strong></td>
<td>Group; outpatient; 24 sessions in 6 wk</td>
<td>30 (18)</td>
<td>Pain</td>
<td>+</td>
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<td></td>
<td><strong>Martin, 1996</strong></td>
<td>Group; outpatient; 3x wk for 6 wk</td>
<td>20 (18)</td>
<td>Pain</td>
<td>+</td>
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<td><strong>McCain, 1991</strong></td>
<td>Group; outpatient; 2x wk for 20 wk</td>
<td>18 (11)</td>
<td>Pain</td>
<td>0</td>
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<td><strong>Mengshoel, 1991</strong></td>
<td>Group; outpatient; 2x wk for 20 wk</td>
<td>15 (11)</td>
<td>Pain</td>
<td>0</td>
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<td><strong>Nicassio, 1995</strong></td>
<td>Group; outpatient; 1x wk for 10 wk</td>
<td>15 (11)</td>
<td>Pain</td>
<td>0</td>
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<td></td>
<td><strong>Nichols, 1994</strong></td>
<td>Group; outpatient; 3x wk for 12 wk</td>
<td>15 (11)</td>
<td>Pain</td>
<td>0</td>
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<td></td>
<td><strong>Norråa, 1997</strong></td>
<td>Group; outpatient; 2x wk for 12 wk</td>
<td>15 (11)</td>
<td>Pain</td>
<td>0</td>
</tr>
<tr>
<td>Author, year</td>
<td>n (completing), mean age (years), % women</td>
<td>Follow-up assessment</td>
<td>Control group, n (completing)</td>
<td>Intervention</td>
<td>Treatment characteristics: individual/group; inpatient/outpatient; duration</td>
<td>Intervention group n (completing)</td>
<td>Outcome measures</td>
<td>Effects</td>
<td>Post</td>
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<tr>
<td>Richards, 2002&lt;sup&gt;23&lt;/sup&gt;</td>
<td>136 (112), 46.5, 92.6</td>
<td>Post 3 mo</td>
<td>Relaxation and flexibility exercises, 67 (55)</td>
<td>Exercise training (aerobic)</td>
<td>Group; outpatient; 2x wk for 12 wk</td>
<td>89 (57)</td>
<td>Pain 0 +</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>van Santen, 2002&lt;sup&gt;24&lt;/sup&gt;</td>
<td>143 (118), 44.7, 100</td>
<td>Post Treatment as usual, 29 (28)</td>
<td>Relaxation (biofeedback)</td>
<td>Individual; outpatient; 2x wk for 8 wk</td>
<td>56 (43)</td>
<td>Pain 0 NA</td>
<td>NA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Schachter, 2003&lt;sup&gt;25&lt;/sup&gt;</td>
<td>143 (102), 41.8, 100</td>
<td>Post Discussion group, 36 (31)</td>
<td>Exercise training (aerobic, long bout of exercise)</td>
<td>Individual; home-based; 1x day, 10–30 min, 1–3 times wk for 16 wk (1)</td>
<td>51 (36)</td>
<td>Pain 0 NA</td>
<td>Dropout &gt;20%</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Thieme, 2003&lt;sup&gt;26&lt;/sup&gt;</td>
<td>63 (61), 47.3, 100</td>
<td>Post 6 mo</td>
<td>Standard treatment education and relaxation, 21 (21)</td>
<td>CBT Group; inpatient; daily during 5 wk (75 h total)</td>
<td>42 (40)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Valkonen, 2005&lt;sup&gt;27&lt;/sup&gt;</td>
<td>26 (26), 59.5, 100</td>
<td>Post Treatment as usual, 13 (13)</td>
<td>Exercise training (aerobic, short bout of exercise)</td>
<td>Individual; home-based; 2x, 5–15 min, 3–5 times wk for 16 wk (2)</td>
<td>56 (35)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Valim, 2003&lt;sup&gt;28&lt;/sup&gt;</td>
<td>76 (60), 45.9, 100</td>
<td>Post</td>
<td>Flexibility exercises, 38 (28)</td>
<td>Exercise training (aerobic)</td>
<td>Group; outpatient; 3x wk for 20 wk</td>
<td>38 (32)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Verstappen, 1997&lt;sup&gt;29&lt;/sup&gt;</td>
<td>87 (72), 45.2, 100</td>
<td>Post Treatment as usual, 29 (27)</td>
<td>Exercise training (aerobic and strength)</td>
<td>Group; outpatient; 2x wk for 6 mo</td>
<td>58 (45)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Vlaeyen, 1996&lt;sup&gt;30&lt;/sup&gt;</td>
<td>131 (105), 44.0, 88</td>
<td>Post 6 mo</td>
<td>Waiting list, 43 (39)</td>
<td>CBT Group; outpatient; 2x wk for 6 wk</td>
<td>49 (36)</td>
<td>Pain 0 NA</td>
<td>Follow-up effects of CBT only in comparison with education and not with control group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>Group; outpatient; 2x wk for 6 wk</td>
<td>39 (30)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wigers, 1996&lt;sup&gt;31&lt;/sup&gt;</td>
<td>60 (44), 44.0, 92</td>
<td>Post</td>
<td>Treatment as usual, 20 (16)</td>
<td>CBT Group; outpatient; 2x wk for 6 wk, 1x wk for 8 wk</td>
<td>20 (13)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Exercise training (aerobic)</td>
<td>Group; outpatient; 3x wk for 14 wk</td>
<td>20 (15)</td>
<td>Pain 0 NA</td>
<td>+</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1 Continued
Cognitive–behavioural therapies and exercise programmes for patients with FM

Effects

Outcome measures

Table 1

<table>
<thead>
<tr>
<th>Treatment characteristics: individual/group; inpatient/outpatient; duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group n (completing)</td>
</tr>
<tr>
<td>Intervention group n (completing)</td>
</tr>
<tr>
<td>Pain</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>58 (52)</td>
</tr>
<tr>
<td>69 (60)</td>
</tr>
<tr>
<td>134 (113), 47.4, 95.5</td>
</tr>
<tr>
<td>134 (113), 47.4, 90</td>
</tr>
</tbody>
</table>

Only four studies carried out additional analyses to identify treatment and patient characteristics that could predict treatment response. The results all concern completers’ analyses with the exception of one study that solely conducted an intention-to-treat analysis. The long-term effect of intervention on pain was evident only at 3 mo, not at the 6-mo and 1-yr follow-ups. This would imply that long-term compliance is crucial in maintaining the positive effects of exercise training. Keel et al. assessed combined multimethod CBT and exercise, found that the individuals who benefited most from the treatment were patients with a significantly shorter history of complaints. These preliminary findings underline the importance of initiating treatment shortly after diagnosis. Sociodemographic and psychosocial variables appeared to be significant predictors of the success of treatment in the intervention study of King and colleagues. However, only a small percentage of the variance was explained by these variables, which may be due to the heterogeneity of FM. In addition, the percentage of responders was very low, suggesting that present treatments are not effective for a large group of patients. The results of this study should be interpreted with caution, due to the high dropout rate.

DISCUSSION

From this review of non-pharmacological treatment in patients with FM, it is apparent that interventions such as CBT and exercise training have a limited effect on the outcome measures, namely, pain, disability and mood. Only a few studies showed improvement after CBT methods and techniques, and even then the positive effects frequently disappeared in the long run. It was mostly multimethod CBT treatments that yielded improvements, suggesting that these are more effective than specific CBTs such as education and relaxation programmes. A recent study by Thieme et al., which evaluated a multimethod CBT programme aimed at behavioural pain treatment, is potentially promising. Their patients reported less pain, disability and psychological distress after treatment, and these results were sustained in the longer term. The findings on exercise programmes indicate that exercise may be useful in reducing disability in daily life on account of patients’ enhanced physical fitness. However, the technique seems less effective in decreasing pain and psychological distress, although trials did show that the fear of patients with FM that exercising will exacerbate their pain was not justified. Exercise training seems to be effective in diminishing disability in daily life but it is unclear whether these effects are maintained for extended periods. Additional psychological maintenance training could help establish long-term compliance with the exercise regimens. Although no evidence was found for the efficacy of a combination of exercise training and CBT, combination treatments have only been incidentally studied. Moreover, the outcomes might be improved if more targeted psychological interventions such as multimethod CBT are used

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in addition to exercise training. Four studies conducted additional analyses to identify those factors that could be vital to improve treatment outcomes. King and coworkers showed that sociodemographic and psychosocial variables were relevant in predicting the success of treatment, but the explained variance was relatively small. The other group, suggesting that early intervention, selection of patients with high levels of distress and tailored treatment as well as continued exercising are promising indicators of the success of treatment.

As for methodological issues, the distinction between single-method interventions such as education and relaxation programmes and multimethod CBT is somewhat artificial. Southgate et al., according to the criteria of the quality of clinical programmes and multimethod CBT is somewhat artificial. For instance, in treatment groups, there is a lack of direct control of the treatment content. Furthermore, the variability within patients is likely to be related to the heterogeneity of the illness and the variability within patients. The current problem could be that all patients with FM are treated with the same commonly accepted interventions, resulting in small overall treatment effects and high dropout rates.

In the next section we will elaborate on the potentially predictive features that may help to enhance the efficacy of non-pharmacological treatments for patients with FM separately, and in relation to studies of other chronic pain conditions. We will conclude the review by offering suggestions for more targeted treatments and future research.

FUTURE DIRECTIONS
Early intervention
The significance of early detection and treatment of patients who are at risk of developing persistent pain and related problems is increasingly recognised. Timing is important for several reasons. Firstly, FM is a condition associated with high levels of pain, disabilities in daily life, psychological distress and diminished quality of life. Intervening early in the course of a disease condition may help prevent the vicious cycle of long-term physical and psychological suffering. Secondly, patients who have had FM for an extended period might have ingrained, maladaptive patterns of pain-coping and illness behaviours that are resistant to treatment, making it more difficult for patients to change their behaviour. Finally, early intervention has the potential to reduce or prevent disability in patients with chronic pain, which, in turn, will reduce societal and medical costs. It follows that early intervention is far more likely to be effective than interventions administered in the later stages of the condition. Non-pharmacological treatments that are initiated shortly after a patient has been diagnosed with FM can help prevent long-term dysfunction and chronicity.

There has been preliminary evidence indicating that early intervention is indeed an important factor in improving non-pharmacological treatment outcomes in FM. Keel et al. showed that a subgroup with a shorter disease duration responded best to treatment. Similar results are also found in other chronic pain conditions. Marhold showed that a cognitive behavioural return-to-work programme proved effective for those patients with chronic pain who were on short-term sick leave but not for patients who had been out of work for longer periods of time. In addition, two interventions for recently diagnosed patients with rheumatoid arthritis (RA) were shown to be effective. Other retrospective findings of studies in RA also demonstrated that patients who were treated shortly after diagnosis responded best to non-pharmacological treatment. Collectively, these findings suggest that early intervention can enhance the efficacy of cognitive behavioural therapies, also for FM.

Patient selection
As stated earlier, the limited effects of non-pharmacological interventions for patients with FM have also been attributed to the variability within patients. Gains in treatment outcome could be achieved if subgroups of patients with FM who are most likely to benefit from a specific treatment are identified. Evidence to this effect has already been reported for RA, showing that specific cognitive behavioural factors are disturbed in patients with a high degree of psychological distress, and that this subgroup of patients benefited from CBT addressing these cognitive behavioural factors. On the basis of psychosocial and behavioural characteristics, specific subgroups can be identified—for example, a dysfunctional group that is characterised by low levels of activity, high levels of pain interference and psychological distress. Previous research revealed that treatment gains could indeed be predominantly attributed to the effects found for such a dysfunctional group—that is, the patients in whom the disease had a higher daily-life impact. Furthermore, in this
review, dysfunctional subgroups of patients with FM also showed the best outcomes during the course of the treatment in three studies but not in one. Overall, it seems to imply that patients with FM have a relatively high level of psychological distress and impact of the disease on daily living are likely to benefit most from non-pharmacological interventions.

Tailoring treatment to the patient’s risk profile

There is some evidence that targeted non-pharmacological interventions that address the specific needs of a particular subgroup are more effective. In his recent overview, Turk supports the notion that results of treatment in patients with chronic pain can be enhanced if treatment is tailored to the patient characteristics, which, according to Thieme and her team, also applies to patients with FM. Treatment can be tailored in various ways, allowing for, among other factors, the demographic, medical, psychological or psychosocial factors of the patients. In patients with chronic pain, including FM, outcomes of pain disability and psychological distress tend to be affected by specific cognitive behavioural factors such as passive pain coping and helplessness.

Only patients with FM who are characterised by these specific cognitive behavioural factors might benefit from interventions that focus on these factors. However, it has to be taken into consideration that in order to improve treatment effects, interventions need to be systematically based on the cognitive behavioural mechanisms proven to be important in FM and chronic pain. More recent CBT interventions that systematically modify key elements of the fear-avoidance model through exposure in vivo, for instance, have yielded promising results in patients with chronic low-back pain. Moreover, the factors typical of specific subgroups may need to be taken into account. For example, in chronic pain, including FM, besides patients characterised by disuse syndrome and passive pain coping, there is also a subgroup of patients that have demanding, non-accepting cognitions and possible overuse, and tailored treatments directed at their specific risk factors might be promising.

Recent developments of approaches aimed at pain acceptance proved relevant in chronic pain, and the subgroup characterised by overuse could particularly benefit from such an approach. Research into other chronic physical symptoms also indicates that treatment tailored to the shared cognitive behavioural factors of subgroups of patients may enhance treatment effects.

Based on these preliminary but promising findings, we conclude that if patients with FM were to be subdivided consistent with their distinctive cognitive behavioural patterns and if interventions were subsequently modified to match these specific risk profiles, the efficacy of non-pharmacological treatment programmes could be substantially taken forward. Future research needs to explore the cognitive behavioural mechanisms relevant in subgroups of patients and develop tailored treatments accordingly.

CONCLUSION

In summary, in spite of wide theoretical and selective empirical support for the rationale of non-pharmacological treatment programmes for patients diagnosed with FM, the studies that were evaluated in this review show their effects to be limited. Preliminary evidence suggests that treatment outcomes could be improved if tailored interventions are offered early to patients at risk of developing chronic physical and psychological impairments. Future research and the clinical practice should respect the heterogeneity and variability in patients with FM and should aim at developing non-pharmacological interventions that best match the needs of the individual patient.

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Competing interests: None.

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