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Rehabilitation approaches in fibromyalgia

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Abstract
Purpose. This paper provides an overview of the evidence for the principal approaches taken to the rehabilitation of patients with fibromyalgia (FM): exercise, psychologically-based approaches, multimodal approaches, self-management approaches, and complementary and alternative therapies.
Method. A review of current published evidence.
Results. Owing to factors such as methodological shortcomings of existing studies, and the lack of evidence on individual modalities, it is difficult to draw definitive conclusions as to which is the most appropriate rehabilitation approach in FM. However, there is growing evidence for the role of exercise training, and clear indications that if appropriately prescribed, this can be undertaken without adverse effects. Similarly, psychologically-based interventions such as cognitive-behavioural therapy have received some support from the literature. Evidence for other interventions is more equivocal.
Conclusions. It appears that a combination of interventions, in a multimodal approach (e.g., exercises combined with education and psychologically-based interventions) is the most promising means of managing patients with FM.

Keywords: *Fibromyalgia, rehabilitation, exercise, psychological interventions, review*

Introduction

Despite a burgeoning literature on fibromyalgia (FM) and its treatment, there is limited empirical evidence for the effectiveness of physical and other non-pharmacological interventions frequently used in the rehabilitation management of the condition. Rehabilitation approaches have, nonetheless, received some support from the scientific literature, generally as part of a multimodal programme. This paper considers the use of rehabilitation interventions in FM and generally addresses those which are considered mainstream conventional approaches, at least within the UK. It provides an overview of the evidence under the general headings of exercise, psychologically-based approaches, multimodal approaches, self-management approaches, and complementary and alternative therapies.

Current therapy practice

Until recently, the practice of physical and occupational therapists in relation to FM has not been clearly documented. Although a number of papers have made recommendations as to appropriate practice in this field [1,2], and case studies have been reported [3], empirical descriptions of practice have been lacking. Two recent surveys have, however, shed some light on this issue.

In a survey of members of two specific interest groups in the UK – the National Association of Rheumatology Occupational Therapists and the Rheumatic Care Association of Chartered Physiotherapists – Sim and Adams [4] sought practitioners' views on management objectives and treatment preferences in FM. Responses were received from 96 out of 140 occupational therapists and 46 out of 61 physical therapists (71% response overall). Occupational therapists most commonly identified increasing functional activities ($n = 29$) as a treatment/management objective, followed by pain management ($n = 20$) and fatigue management ($n = 14$). Physical therapists most commonly nominated increasing exercise tolerance and fitness ($n = 29$), followed by reduction of pain ($n = 21$) and improving functional ability ($n = 14$). Respondents, across both professions, reported fatigue management and endurance exercise as the most frequently utilized interventions, followed by functional activity

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re-education, postural education, relaxation, strengthening exercise, and hydrotherapy.

McVeigh et al. meanwhile, conducted a survey of physical therapists in Northern Ireland [5]. Whereas Sim and Adams [4] targeted specialist practitioners, McVeigh et al. surveyed therapists working in outpatient settings. From a sample of 106, a total of 75 (71%) responded. The authors estimate that this figure represents approximately half the physical therapists working in this treatment setting in Northern Ireland. Respondents' most commonly reported treatment goals were increasing daily function ($n = 24$) improving patient education ($n = 22$), and reducing pain ($n = 18$). The treatment approaches most commonly identified were exercise ($n = 44$), hydrotherapy ($n = 12$), pain management programme ($n = 5$), and electrotherapy ($n = 4$).

The role of rehabilitation, at least as practised in the UK, appears to centre on strategies to promote exercise, restore or re-educate function, and manage pain. It is recognized that practices in other countries may vary and may include holistic practices as part of mainstream therapeutic approaches.

Mechanisms of pain transmission in FM and rationale for treatment approaches

It has been hypothesized that FM is a disorder of the mechanisms related to pain processing at both a central and a peripheral level, resulting in a situation of generalized hyperalgesia. Several neurochemical and neurohormonal alterations have been described in these patients that could justify and explain part of this hypothesis [6]. The presence of widespread pain in muscular areas, muscular weakness, fatigue and stiffness reported by these patients suggests that an underlying pathology could be present and some morphological and functional studies carried out on muscle and tender points have shown a series of structural, biochemical and functional alterations. However, these are not unique to FM and can be observed in other processes.

Strategies for FM management should be based upon an understanding of neurophysiological, neuropsychological and neurochemical mechanisms of pain transmission systems and their various interaction, and appraised and implemented on the basis of their relationship to these mechanisms [7–9].

One of the most commonly observed functional alterations in FM patients is poor levels of physical fitness, characterized by a lesser capacity to perform physical exercises and an increasing tendency to fatigue on usual activities. Whether this poor physical fitness is produced by the lack of physical activity, or whether it results from an 'illness' of the musculoskeletal system, has not yet been elucidated. In any case, it has been shown that aerobic capacity and muscular strength can improve after programs of physical training without detrimental effects to the patient (see later section).

Most clinical trials with drugs, although useful to improve clinical symptoms, have been carried out for short periods of time. Further follow-up studies are required to ascertain their value over extended time periods, though some studies have indicated that FM patients abandon their medication because symptoms do not change despite long term treatment.

Non-pharmacological studies have been promising and have been supported by a recent meta-analysis [10]. Several clinical trials have shown an improvement in symptoms of FM patients treated with physical exercise, though maintenance of long-term effects, adherence, and its suitability for all patients are issues to consider when prescribing exercise for these patients. Other non-pharmacological interventions used in the management of FM are physically-based approaches, psychologically-based strategies and complementary and alternative medicine approaches. This paper will provide a review of these approaches.

Exercise

Perhaps unsurprisingly, in view of the pain and fatigue that characterize the syndrome, most patients with FM are physically deconditioned [11]. The evidence for various types of exercise interventions in FM has been growing in recent years, though systematic reviews have not provided an unequivocal indication of their benefits [12,13]. Programmes aimed at increasing strength, endurance and flexibility have been tested in various combinations, and against a number of other interventions.

A number of exercise programmes tested on patients with FM have employed more than one type of exercise. For example, in relation to tender point score, total myalgic score and aerobic fitness, Martin et al. [14] reported superior benefits for an exercise programme ($n = 18$), incorporating aerobic, strengthening and flexibility elements, compared to a relaxation programme ($n = 20$). Long-term effects are unclear, however, as follow-up was limited to six weeks. Verstappen et al. [15] compared a six-month group activity programme ($n = 58$), comprising flexibility, strengthening and aerobic endurance exercises, with a no-treatment control group ($n = 27$) that continued 'normal activity'. The exercise group showed improvement in physical fitness compared to the control group.

A Canadian study randomized patients with FM to an exercise group ($n = 27$) or a control group ($n = 24$) [16]. The exercise regimen consisted initially of stretching and aerobic exercises, in a pool, and after seven weeks included walking classes. On intention-

to-treat analysis at 23 weeks, the exercise group performed significantly better than the control group in terms of a six-minute walk and the Beck Depression Inventory. Differences were also witnessed in favour of the exercise group in anxiety, Mental Health Inventory scores, Fibromyalgia Impact Questionnaire scores, and self-efficacy.

A descriptive study by Tiidus and colleagues utilized a ten-week community-based programme of aerobic, strength and stretching exercises [17,18]. Fourteen women were recruited to the programme. Significant improvement was seen in mood, tender point count, and walking speed, but not in work capacity or flexibility. Inferences as to the effectiveness of the programme are limited, however, by the lack of a control group. In another uncontrolled study of 15 female patients, Rooks et al. [19] found improvements in strength, six-minute walk distance and the Fibromyalgia Impact Questionnaire, following a 20-week programme of strength and cardiovascular exercises. Of particular note in this study is that the programme was well tolerated by participants, with high adherence and no injuries.

A recent randomized study by Jones and colleagues focused specifically on strengthening exercises [20]. Women were randomized to a 12-week programme consisting of either strengthening ($n = 28$) or flexibility exercises ($n = 28$). No significant between-group differences were found on any outcome variable, though each group showed significant improvements. The muscle strengthening regimen did not cause flare-ups in participants' pain. There is evidence from other work that women with FM are as capable of gaining physiological benefits, in terms of maximal and explosive strength and electromyography, as healthy women [21].

Several studies have focused on aerobic exercise. In a small randomized study, Nichols and Glenn tested an eight-week programme of aerobic exercise at 60–70% predicted maximum heart rate ($n = 10$) against a 'sedentary' control group ($n = 9$) [22]. The only significant improvement in the exercise training group was in the Positive Symptom Total subscale of the Brief Symptom Inventory, though there were other non-significant improvements. The overall effect of the exercise programme is unclear, however, owing to the small sample size.

McCain et al. tested a 20-week programme of either cardiovascular fitness training ($n = 18$) or flexibility exercises ($n = 20$) [23]. They found improvements in cardiovascular fitness and pain threshold scores in the cardiovascular training group, but no differences in pain intensity or sleep disturbance. Mengshoel et al. conducted a randomized comparison of a 20-week low-impact aerobic dance programme ($n = 11$) and a control group ($n = 14$) in which there was no change in activity [24,25]. No between-group differences were found. Nor were differences found in a later study [26] between patients randomized to either an aerobic dance training programme ($n = 15$), a steady exercise programme ($n = 15$) or a control condition consisting of the application of hot packs ($n = 8$). Dropout in this study was, however, high at 39% and no intention-to-treat analysis was performed.

Wigers and co-workers randomized patients to a 14-week-programme of either aerobic exercise ($n = 20$), stress management training ($n = 20$), or usual care ($n = 20$) [27]. The exercise group showed superior responses to one or both of the other groups in pain distribution, pain intensity, energy and work capacity, though only the stress management group showed improved depression scores in comparison to the usual care group. In the UK, Richards and Scott compared prescribed graded aerobic exercise ($n = 69$) and a control treatment consisting of relaxation and flexibility ($n = 67$) [28]. Significantly more patients in the exercise group rated themselves as 'much better' or 'very much better' at three months, and this group had significantly better outcomes than the control group on tender point counts and the Fibromyalgia Impact Questionnaire. It is of interest that these results were obtained using personal trainers with no specialist experience in clinical exercise training, and that no adverse events were recorded.

Meiworm et al. compared 27 patients undergoing aerobic exercise training with 12 sedentary controls [29]. The exercise group undertook a self-managed programme of walking, jogging, cycling and swimming, for an average of 25 minutes, two to three times a week. Although there were significant improvements on physiological indices in the treatment group, the lack of between-group analyses, and the fact that participants were not randomized to the arms of the study, does not allow firm conclusions to be drawn.

A few studies have focused on differing levels of exercise intensity, or different contexts or modes of delivery of an exercise programme. In a study by Meyer and Lemley, participants were randomized to a high-intensity exercise group ($n = 8$), a low-intensity exercise group ($n = 8$), or a control group ($n = 5$) [30]. The exercise groups undertook a 24-week programme of walking, of increasing intensity, whilst the control group were asked to maintain their usual level of activity. No between-group differences were found during the 24-week exercise period, and the three groups were therefore combined for a within-group analysis. This analysis showed a significant 11.2% increase in resting heart rate, and a significant 10% decrease in exercise heart rate. However, no inferences as to the relative effects of

high- and low-intensity exercise can be drawn from this study. Schachter et al. examined the effect of using either short or long bouts of exercise (fractionation) for women with FM [31]. Participants were randomized to a long-bout exercise group ($n = 51$), a short-bout exercise group ($n = 56$), and a no-exercise control group ($n = 36$). There were no differences between the short- and long-bout exercise groups. The short-bout exercise group differed from the no-exercise group at 16-weeks follow-up in terms of physical function variables, but these two groups differed in this respect at baseline also.

In a recent study from the Netherlands, women with FM were randomized to either high intensity ($n = 19$) or low-intensity ($n = 18$) fitness training [32]. In neither group were there noteworthy changes, other than an increase in pain in the high-intensity group, and only in respect of the 'pain' dimension on the Arthritis Impact Measurement Scales did the two groups differ significantly, in favour of the low-intensity group.

A UK study by Ramsay et al. [33] compared a supervised cardiovascular fitness training programme ($n = 37$) with a single aerobic exercise session that was continued unsupervised in the patient's home but reinforced by written instructions ($n = 37$). At 12 weeks from baseline, the supervised exercise group showed significantly greater improvement in anxiety than the unsupervised group.

Exercise in water (hydrotherapy) is commonly used for patients who are in pain, such as in FM [34], as the warmth and buoyancy of the water helps to minimize pain while performing exercises. This is reflected in Offenbächer and Stucki's recommendation that exercise in FM should have low-impact loading [35]. These authors also suggest that water exercises are an appropriate starting point for patients who are very deconditioned.

Jentoft et al. randomly allocated patients to a pool-based ($n = 18$) and a land-based ($n = 16$) aerobic exercise programme [36]. Only in respect of grip strength was there a significant between-group difference at 20 weeks, in favour of the land-based exercise group. Within-group improvements were noted for both groups in relation to fatigue, stiffness, cardiovascular capacity and walking time. As the mean duration of FM in both groups at the outset of the trial was 11 years, it is reasonable to assume that these within-group changes are unlikely to represent spontaneous clinical improvement.

An earlier study by Mannerkorpi and colleagues compared patients receiving a combination of hydrotherapy and education ($n = 28$) with a control group ($n = 30$) [37]. At the end of the six-month treatment period, the treatment group scored significantly better than the control group in terms of the total score on the Fibromyalgia Impact Questionnaire and six-minute walk. Improvements in the treatment group in respect of symptom severity, physical function and social function were sustained six and 24 months after the end of the study [38]. The long-term effects in this study may be due to patients continuing to take part in forms of exercise beyond the end of the trial [39], which is an important consideration in a chronic condition such as FM.

Patients report fatigue and pain as barriers to exercise [40]. Rosen suggests that patients should be forewarned of the possibility of an increase in pain and encouraged to persevere with the programme notwithstanding [41]. In this connection, Offenbächer and Stucki [35] propose that the aim of an exercise programme should be functional restoration, not pain relief. Accordingly, Mengshoel [42] advises that the therapist should not promise to reduce pain, as might be possible in cases of acute pain. Gowans and deHueck [43] make the following specific recommendations:

- Exercise should start just below participants' capacity and increase gradually until it is at the lower end of moderate intensity.
- Participants should be made aware of tolerable short-term increases in pain and fatigue, but be reassured that these will return to baseline levels within a few weeks.
- Their capacity to exercise should be increased in due course, with the same or lower levels of pain.

In terms of exercise progression, fluctuations in patients' pain from day to day may require appropriate adjustments to be made – a linear increase in exercise intensity may not be possible [44]. Furthermore, given the variability in patients' symptoms and functional limitations, exercise regimens should be individualized to the patient's baseline function, symptom severity and tolerance of exercise-induced pain [39]. Pain relieving modalities can usefully be employed in conjunction with exercise [35,45]. If exercise is prescribed appropriately, it can be performed without aggravating the patient's symptoms, especially if self-paced [46]. High-intensity exercise, however, should be utilized with caution [39]. If exercise-induced pain occurs, Mannerkorpi and Iversen [39] suggest that the frequency of exercise should be maintained, so as not to further decrease exercise tolerance, but its intensity and/or duration should be reduced.

Although the support for exercise training is perhaps more theoretical than empirical at present, it is a potentially important treatment avenue, and an area in need of further investigation.

Educational, psychophysiological, and cognitive-behavioural treatments

A main objective of these psychologically-based therapies is to address issues of pain perception, to teach management skills for pain and disability, and to ensure patients' are able use the skills successfully.

Various techniques used in the management of FM are based on patient education, with the aim of reducing anxiety, increasing compliance with treatment, improving coping behaviours and self-efficacy and refocusing attention away from symptoms to improved function and quality of life [47, 48]. Patients with higher self-efficacy are more likely to respond favourably to treatment programmes and experience better outcomes than those with low self-efficacy [49]. Many patients believe that they cannot control the pain, disability and negative effects of their condition and this, in turn, results in increased distress, pain and sleep problems. Also, patients reduce their engagement in activities of daily living and in developing effective coping behaviours and cognitions.

Psychological interventions involve the interrelationship between physical and psychological aspects in illness. Two major approaches are psychophysiologically-based therapies (PPT), such as EMG biofeedback, and interventions based on cognitive-behavioural therapy (CBT). The basic tenet of PPT is the attempt to change cognitions through the manipulation of physiological responses, e.g. by electromyography, whereas in CBT the attempt is to change physiological responses through the manipulation of cognitions [49]. CBT is intended to assist patients in feeling in control of their condition. A biopsychosocial model of FM incorporating stress, sleep disturbance, fatigue, cognition, rumination and negative affect has been described as a method of understanding how this therapeutic approach may be successful in improving symptoms [50].

Education and CBT are different by definition; however, in the clinical setting they are difficult to differentiate. Thus they are grouped together for the purposes of this review.

Electromyographic biofeedback training

Electromyographic (EMG) biofeedback training is a PPT that has been used in the physical management of chronic musculoskeletal pain [51,52], but to a lesser extent in the UK. In studies carried out on 15 patients with FM, consisting of 15 sessions of biofeedback training over a five-week period and using relaxation training with an acoustic signal, Ferraccioli et al. found improvements in number of tender points, pain intensity and morning stiffness [53]. Patients were found to have maintained these improvements at six-month follow-up. A randomized controlled trial was also conducted as part of the same study, with 'sham' biofeedback as the control. However, the small numbers in the study ($n = 6$ in each group) and the lack of between-group analyses make it difficult to draw conclusions regarding the effectiveness of the intervention.

Buckelew et al. conducted a larger randomized study comparing biofeedback/relaxation ($n = 29$) with exercise ($n = 30$), combination therapy comprising biofeedback/relaxation plus exercise ($n = 30$), and an educational group as a control ($n = 30$) [54]. Each of the active conditions demonstrated significant within-group improvements regarding pain, pain behaviour and self-efficacy, but there were limited and statistically non-significant between-group differences. Issues such as patient adherence to exercise may have affected the results, as only part of the exercise programme was supervised. The authors noted that improvements in self-efficacy were associated with better outcomes on all measures, which concurs with extant literature.

Van Santen et al. carried out a randomized controlled trial (RCT) on patients randomized to either a fitness programme ($n = 58$), biofeedback training ($n = 56$) or a usual care control group ($n = 29$) [55]. Although there were some within-group changes, there were no significant differences found between groups on any of a comprehensive range of outcome measures, which included pain, number of tender points, total myalgic score, physical fitness, functional ability, psychological distress, patient global assessment and general fatigue. The authors concluded that compared to usual care (analgesics, non-steroidal anti-inflammatories, tricyclic antidepressants, physiotherapy and medical counselling), there were no clear beneficial effects of fitness training or biofeedback training on objective or subjective outcomes. However, it could be argued that the usual care control group was in fact a multimodal approach, with which better outcomes have often been associated (see later section).

Molina et al. [56] indicated that EMG biofeedback training reduced plasma ACTH and beta-endorphin during treatment, indicating a possible opioid or neuroendocrine basis for some of its observed beneficial effects, particularly with regard to FM patients. Sim and Adams [4] found biofeedback to be infrequently used by therapists in the UK, probably due to lack of specialized training and/or unavailability of suitable equipment and also due to a tendency to favour combined interventions such as exercise and CBT-based pain management programmes.

Education, behavioural interventions and cognitive-behavioural therapy

Patient education has long been an important component of rheumatic disease care and beneficial outcomes have been reported from educational interventions for FM. Burckhardt and colleagues randomized women with FM to either education ($n = 31$), education and physical therapy ($n = 33$) or a delayed treatment control group ($n = 35$) [47]. They found that all dimensions of self-efficacy were enhanced in patients who participated in the education and physical therapy group, and the function dimension of self-efficacy increased in the education group when compared with the control group.

Gowans et al. randomly allocated patients to either a six-week programme of combined education and pool-based exercise ($n = 20$) or a waiting list control group ($n = 21$) [57]. The education group demonstrated greater improvements in physical function, wellbeing, fatigue and knowledge about FM immediately following the programme, though improvements in fatigue and knowledge were not maintained at three-month follow-up. No differences in self-efficacy were found between the groups.

Cognitive behavioural and behavioural interventions for FM have been reported to lead to improvements in terms of pain ratings, other clinical symptoms, functional disability, pain behaviour and tender point measures. However, these findings should be interpreted cautiously because of lack of control of non-specific effects [58]. Vlaeyen and colleagues randomly allocated patients with an average pain duration of 10.2 years to either an education-cognitive group ($n = 49$), an education discussion group ($n = 39$) or a waiting list control ($n = 43$) [59,60]. They found within-group differences for both the active interventions but no between-group differences between these two groups on pain intensity, pain control and coping, knowledge of FM, and affect. More favourable results were noted for the discussion group, which may have been due to increased social support and fear reduction. Thus, social support may be an important mediating factor in FM, and may explain improvements with multimodal group therapy (see subsequent section).

In a methodologically rigorous study by Soares and Grossi [58], a randomized comparison was conducted of an educational intervention ($n = 18$), a behavioural intervention ($n = 18$), and a waiting list control group ($n = 17$). Patients were assessed across a ten-week treatment period and at six-month follow-up. No significant changes were reported for the educational intervention group. The behavioural intervention group reported benefits on patients' use of pain coping strategies, functional disability, perceptions of pain and quality of sleep. However, with the exception of sleep quality, these gains were not maintained at follow-up. Some deterioration in outcome measures was reported in the waiting list group. The authors concluded that there were essentially no differences between the three conditions in terms of effectiveness, though noted that the chronicity of the participant group and the reliance on subjective patient reports in the outcome measures may have influenced the results.

Nicassio et al. compared a behavioural intervention ($n = 48$) consisting of education, relaxation, goal setting, pacing and use of a support person over a ten-week period with an education group ($n = 38$) receiving group discussion and support over a similar time period [61]. Statistically significant changes were found within groups for pain behaviour, depression, disability, helplessness, pain coping and myalgic score, but there were no significant between-group effects.

A recent study on female patients with FM by Redondo et al. [62] compared CBT ($n = 21$) with a physical exercise-based strategy ($n = 19$), and found that functional ability improved significantly in the physical exercise group compared with the CBT group. However, there were no differences within or between the groups in terms of anxiety, depression or self-efficacy. At a follow-up period of one year, most parameters had returned to baseline with the exception of functional ability in the physical exercise group. Improvement in self-efficacy and physical fitness was not found to be associated with improvement with clinical symptoms and it appears that these interventions only improve the clinical symptoms of FM for a short period of time. Similar findings have been reported in a meta-analysis of CBT-based therapies by Kendall et al. [63], where the authors found no consistent or large sustained effects of CBT as a single therapy. Williams argues that CBT produces modest outcomes (rather more modest than in other chronic pain syndromes) across a range of domains, including pain, fatigue, physical functioning and mood [64]. He further argues that CBT should not be regarded as a fall-back strategy for when other approaches have failed, but should be implemented at an early stage.

In summary, interventions with CBT designed to improve cognitive and behavioural aspects have proved useful in the treatment of FM, though generally as part of multimodal programmes that have combined CBT with physical exercise rather than through CBT alone (see later section). However, different authors use differing classifications and techniques of CBT within their programmes and thus comparison across cognate studies is often difficult.

Self-management education programmes

Ostensibly these programmes use the same or similar techniques to CBT, but may be multimodal in nature (see following section) and emphasize self-management, the aim being a well-informed patient at the centre of the management team [65]. The key elements of successful self-management programmes for FM include education about the syndrome and an emphasis that the patient is central to the management team. Much of this approach has been developed from programmes devised for patients with arthritis [66], and the goals of these programmes include assisting the patient to assess the activity of the condition, determining the appropriate level of treatment, and alerting them when to seek medical attention [67].

Mengshoel et al. enrolled 16 women with FM on a ten-week programme [68]. In addition to an exercise regimen and relaxation techniques, participants received education about FM, and group discussions and advice on daily living, goal-setting and problem-solving activities. Significant improvements occurred in certain pain dimensions, and 80% of participants rated the different components of the programme to be of 'benefit' or 'great benefit'. These findings must, however, be viewed with regard to the uncontrolled nature of this pilot study.

Hunt and Bogg randomized patients with FM to a self-management programme ($n = 25$) or a control group ($n = 25$) [69]. The self-management programme included psychological, educational and physical (exercise) approaches. Pain, perceived exertion and attitude to condition improved significantly in the treatment group, whilst no significant improvements occurred in the control group. However, the lack of any between-group analysis at post-test prevents clear conclusions from being drawn from this study. More recently, Cedraschi et al. evaluated the efficacy of a treatment programme for FM patients based on self-management using pool exercises and education [65]. Patients were randomly allocated to either a six-week programme ($n = 84$) or to a waiting list control group ($n = 80$). In total, 129 patients completed the study and at six-month follow-up, significant improvements in fatigue, depression, quality of life and functional consequences of FM were found in the treatment group as compared with the control group. Patient satisfaction was also enhanced by the programme. No differences for pain were found.

There is, as yet, little evidence on which to base conclusions as to the effectiveness of self-management programmes. It should be noted, however, that other approaches, classified under different headings in this review, may include self-management among their objectives, and may thereby lend indirect support to this approach.

Multimodal/combination treatment approaches

Multimodal treatment approaches adopt a multidimensional approach to the management of FM and are usually delivered in a multidisciplinary setting. Components of treatment already mentioned, such as exercise, CBT, and education, may be included in these programmes, in addition to specific manual techniques and medication [48]. Such multimodal interventions have received support from recent reviews [13,70].

Several authors describe management programmes that include the following:

- Patient education.
- Pain relief (physical).
- Pain relief (medication).
- Stress management.
- Aerobic exercise.
- Sleep therapy.
- Psychological intervention (e.g., coping skills).

Nielson et al. conducted a quasi-experimental study of a comprehensive three-week in-patient multimodal therapy programme for 25 patients with FM [71]. The programme consisted of relaxation assisted by biofeedback, cognitive restructuring, aerobic exercise and stretching, pacing and enhancement of pain tolerance, and family education. Although participants were found to have improved pain severity, pain control, emotional distress and functional ability, the small numbers of patients and short observation period limit the external validity of the results. A subsequent follow-up study reported improvements to be maintained at 30 months [72].

In a descriptive study evaluating 104 patients with FM participating in weekly group sessions over 6 months, compared with 29 non-participants, Bennett et al. [73] showed a significant decrease in number of tender points and improvement in FIQ scores, pain, fatigue, stiffness and physical function. Further, these gains were maintained at two-year follow-up. Although the results of this study are encouraging, the study was uncontrolled and all outcome measures unblinded.

Keel et al. randomly allocated patients to either an integrated group therapy programme ($n = 16$) or group relaxation ($n = 16$) [74]. The integrated group therapy programme comprised various self-help techniques (including cognitive behavioural techniques), information, active exercises, relaxation and group discussion. At four-month follow-up the experimental group demonstrated lower mean pain intensity scores than the control group. However,

while this difference was statistically significant, it was of small magnitude.

Turk et al. studied the effects of a four-week interdisciplinary treatment program delivered on an out-patient basis to 67 patients [75]. The programme included education, exercise therapy (physical therapy), functional re-education (occupational therapy) and CBT. Patients showed improvement in pain severity, anxiety, depression, affective distress and fatigue at the end of the programme and maintained these gains at six-month follow-up, with the exception of fatigue. The authors identified that high levels of distress, perceived disability, solicitous responses from significant others, low level of perceived control and traumatic onset appeared to be predictive of a poor response to intervention.

Mason et al. evaluated an intensive multimodal treatment programme which combined CBT with physical therapy and medication for pain reduction [76]. Patients were allocated to either a treatment group ($n = 11$) or a comparison group ($n = 12$) of non-participants. The programme consisted of a full-day intervention, six days a week for one month. Physical therapy was carried out for four hours per day and consisted of aerobic, strengthening and flexibility exercises, postural and biomechanical re-education, ice massage and 'spray and stretch' techniques to tender points. CBT consisted of two hours daily of education, cognitive reinterpretation and reduction of pain behaviours. Diaphragmatic breathing, progressive muscle relaxation, hand warming, guided imagery and distraction techniques were also carried out to reduce muscle tension and sensory nervous system arousal. The treatment group showed a significant improvement on psychological and self-report measures (pain, coping, Fibromyalgia Impact Questionnaire and depression) but not on the laboratory measures (cold pressor test and dolorimetry). However, these gains were not maintained at six-month follow-up, possibly due to patients' lack of adherence to instruction and advice. The authors concluded that improvements in FM may depend upon factors such as increased endurance and more effective coping skills rather than upon changes in physical aspects.

A recent descriptive study by Pfeiffer et al. [77] of a multidisciplinary out-patient programme for patients with FM ($n = 78$) found significant improvements one month after treatment in impact of illness, assessed by the Fibromyalgia Impact Questionnaire, following an intensive multimodal programme consisting of education, self-management using cognitive behavioural techniques, occupational therapy and physical therapy, conducted over 1.5 days. However, no improvements in depression or life fulfillment were found.

A non-randomized controlled study by Gustafsson et al. [78] allocated patients either to a multidisciplinary rehabilitation programme ($n = 23$), involving physiotherapy, body awareness therapy, relaxation, education, group discussion, and individual guidance on coping strategies, or to a waiting list control group ($n = 20$). The rehabilitation programme group showed improvement in the Body Awareness Scale – Health, whereas the control group showed deterioration. No direct between-group comparisons were performed, however, and the effectiveness of the programme is therefore uncertain. An uncontrolled study by Bailey et al. [79] evaluated a 12-week interdisciplinary group education and exercise programme, in which 149 patients were advised on disease and stress management, with an emphasis on self-management, and given an exercise programme to improve general fitness. The programme was completed by 106 patients. With the exception of grip strength, all outcomes improved significantly – these included measures of pain, physical fitness, self-efficacy and coping. The results of this study are promising, though the lack of a control group limits the formal inferences that can be drawn as to treatment effectiveness.

Although a multimodal programme with a combination approach is widely advocated in clinical practice for FM and has received some support from a systematic review [13], the lack of standardization across the different programmes and heterogeneity of their content, in addition to methodological constraints of the studies themselves, make if difficult to provide a definitive assessment of their effectiveness. There is also a marked lack of controlled studies in this approach to management. Further, in future studies, subgroups of patients may need to be identified based upon the relative contributions of physiological, psychological and cognitive factors to symptom expression [80–82]. This may identify patients who are likely to benefit most from specific rehabilitation programmes, such that approaches may be adapted accordingly.

Complementary and alternative therapies

Patients with FM have been found to have high rates of complementary and alternative therapies usage [83,84], and a number of interventions have been tested that fall under this general label. Among these are holistic movement therapy, energy therapy, balneotherapy, and osteopathic and chiropractic manipulation.

Holistic movement therapies

Several therapies may be classed as a holistic movement therapy and are widely practised in parts of

Europe as part of physical therapy, though they are not routinely used in the UK, where they would be classed as complementary and alternative medicine. In Body Awareness Therapy (BAT), which is taught in Swedish physiotherapy colleges, a combination of psychological and physiological techniques are taught to increase awareness of muscular tension and relaxation, posture, movement and breathing, combined with an awareness of the psychological response to these movements. Coping skills and stress management also form part of this intervention. Thus the aim is to raise body consciousness in order to increase the individual's capacity to control painful movements (body management) and to assist the patient to utilize his or her own resources (deepened body experience), thereby leading to increased daily functional capacity [85]. In a pilot study comparing BAT ($n = 10$) with another form of holistic physical therapy ($n = 10$), for which the aim was to increase functional capacity through cognitive and behavioural components (Mesendieck system), between-group comparisons indicated that the Mesendieck system intervention was more effective than BAT [85]. The rehabilitation programme in the study by Gustafsson et al. [78], reviewed in the previous section, also included BAT.

Results of a descriptive pilot study of an eight-week intervention for FM patients ($n = 28$) on the practice of mindfulness meditation and another movement therapy (Qigong) showed significant reductions in pain, fatigue, sleep disturbance and depression, as well as reductions in tender point scores, that were maintained at 24-week follow-up [86,87]. Astin et al. carried out a RCT to test the short and long-term effects of mindfulness meditation plus Qigong therapy ($n = 64$) compared with an education support control group ($n = 64$) [88]. Within-group improvements were noted for both groups for pain, disability, pain and depression; however there were no between-group differences. Thus there is no evidence at present to suggest that this is a superior intervention to education support alone.

Mannerkorpi and Arndorw combined body awareness with Qigong in a study of women with FM randomized to either a body awareness and Qigong group ($n = 19$) or to a control group ($n = 17$) [89]. They found a significant improvement in body harmony (measured by an observational method called the Body Awareness Rating Scale) in the treatment group; however a deterioration for fatigue and depression (assessed by the Fibromyalgia Impact Questionnaire) was noted for both groups. Lengthy periods of standing in the Qigong part of the programme worsened symptoms. The authors concluded that this form of therapy is probably not suitable for patients with FM and that in future programmes the movements should be performed while changing position.

Energy therapies

The US National Institutes of Health requested proposals for clinical trials to examine the efficacy of magnet therapy due to its increasing popularity in some countries for the treatment of chronic pain [84]. Magnetic therapy is the only energy therapy that has been evaluated in FM. Energy therapies have hitherto received little scientific attention in the UK.

Biological effects of static magnetic fields have been found to include inhibition of pain signals, effects on nerve-growth-factor-stimulated neurite outgrowth in PC-12 cells, production of reversible changes in presynaptic membrane function and induction of immune and vascular responses [90]. However, the precise mechanism of action of static magnetic fields is not understood.

Two randomized placebo controlled trials of static magnetic fields for FM have been conducted. Colbert et al. compared 16 weeks of sleeping on a magnetized mattress ($n = 15$), compared with a placebo group ($n = 15$) who slept on a sham-magnetized mattress [91]. Patients in the magnetized mattress group showed improvements in pain, sleep, fatigue, tiredness on waking, total myalgic score, body pain distribution and physical function. The placebo group showed only improvement in tiredness on waking. However, there were no between-group post-test analyses conducted and there was no follow-up beyond the end of the treatment period.

Alfano et al. [90] carried out a placebo controlled RCT on 119 patients who were randomized to one of five conditions: two functional magnetic pads (A and B) with differing polarities and placements, two sham groups that contained inactive magnets and a usual care group which continued with established treatment regimens, though it is not specified what these entailed. At six months, pain intensity ratings differed between groups, with the greatest reduction from baseline occurring in the group receiving a functional pad providing a low, uniform static magnetic field of negative polarity (condition A). However, the groups were similar with respect to function, tender point counts and tender point intensity.

Findings from clinical studies and evidence of biological effects suggest that magnetic fields may warrant further investigation, though these studies offer limited evidence for their use in FM.

Balneotherapy

Balneotherapy (warm mineralized baths) has long been used to treat rheumatological illness. The

mechanism is not fully understood but it is known that physiological changes brought about by immersion in water, including hydromechanical and thermal stimuli, affect muscle tone, joint mobility and pain intensity, which are symptomatic of FM. Yurtkuran and Celiktas evaluated balneotherapy ($n = 20$) against relaxation exercises ($n = 20$) in patients with FM [92]. The authors found significant within, group improvements in pain and algometer scores in the balneotherapy group immediately post-intervention and at two, and six-week follow-ups. Similar effects, but of lesser magnitude, were found in the relaxation group. No between-group analyses were performed, which limits the findings of the study.

In a later study, an Israeli team randomly assigned patients with FM to either daily 20-minute sulphur spa baths with water from the Dead Sea ($n = 24$) or to a control (no treatment; $n = 24$) over a ten-day period [93,94]. Both groups continued with their usual medication and both demonstrated improvements in outcome measures including physical functioning and tender point scores, though of greater magnitude in the treatment group, and these gains were maintained at three-month follow-up. Quality of life also improved in both groups, and the improvement in physical domains of quality of life was longer lasting than that in psychological measures. The finding that the no treatment group also improved over a ten-day period may in part be attributed to the effects of staying at a spa resort. The effects of hot water baths alone were not considered and a placebo-controlled RCT (using hot water baths alone) is indicated as an area for future research.

Osteopathic and chiropractic manipulation

Osteopathy and chiropractic are treatment approaches that utilize joint manipulation. Although practitioners of these systems are increasingly gaining acceptance within orthodox medicine, they are still generally classed as complementary or alternative approaches. These techniques are intended to reduce pain, enhance muscle strength and joint mobility, provide proprioceptive training, and limit further joint and muscle damage [95]. A common criticism of these techniques is that although they may be effective in reducing pain and increasing mobility, the effects may be short-lived. Chiropractic and osteopathy have become popular in the treatment of acute conditions, though there is little scientific evidence regarding their effectiveness in chronic conditions.

An RCT of patients with FM randomized to either chiropractic manipulation ($n = 10$) or a waiting list control ($n = 9$) found significant improvement in tender points over a four-week treatment period in the treatment group in spinal mobility and pain [96]. However, there were several limitations of the study, including small sample size, likely bias and possible influence of extraneous variables. It should also be noted that chiropractic treatment consisted of soft tissue massage, exercise, manipulation and education and may have been better classed as a combination therapy.

A study by Gamber and colleagues [97] of 24 patients with FM randomly assigned to one of four treatment groups – manipulation, manipulation and teaching, moist heat, or a control group (standard medical care) – found significant improvements in pain, activities of daily living and chronic pain attributes in the treatment groups with manipulation. However the small sample size and lack of follow-up data make it difficult to form definitive conclusions. Thus the evidence for chiropractic and osteopathic intervention is insufficient and additional, larger RCTs are warranted.

Conclusion

It is difficult to draw definitive conclusions as to the most appropriate rehabilitation approach in the management of FM for a variety of reasons, such as methodological constraints of the available studies, and the heterogeneity and lack of standardization of programmes, which makes comparison across cognate studies difficult. However, an increasing number of methodologically rigorous studies have provided evidence for the use of exercise in the management of FM. Psychologically-based interventions such as CBT have also proved useful in the management of FM as part of a multimodal programme when combined with exercise, rather than by CBT alone. The fact that evidence of effect of many interventions, particularly with regard to complementary and alternative therapies, is scant does not mean that such effects are absent [98]. Encouraging preliminary results have emerged for the use of some complementary and alternative therapies, though further research is required to demonstrate evidence of effectiveness.

Identification of subsets of FM patients may be an important factor in selecting an appropriate rehabilitation intervention. The subjective responses of patients to rehabilitation interventions, and the acceptability of these interventions in terms of their beliefs and lifestyles, have received scrutiny [40,99], but further work is warranted here.

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