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An observer-blinded comparison of supervised and unsupervised aerobic exercise regimens in fibromyalgia

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Abstract

Objective. To compare a supervised 12-week aerobic exercise class with unsupervised home aerobic exercises in the treatment of patients with fibromyalgia.

Methods. This was a 48-week randomized single (observer) blind study in a teaching hospital rheumatology and physiotherapy department. The subjects were 74 patients who fulfilled the American College of Rheumatology criteria for fibromyalgia.

Results and conclusions. A 12-week exercise class programme with home exercises demonstrated no benefit over a single physiotherapy session with home exercises in the treatment of pain in patients with fibromyalgia. Neither group (nor the groups combined) showed an improvement in pain compared with baseline. There was some significant benefit in psychological well-being in the exercise class group and perhaps a slowing of functional deterioration in this group.

KEY WORDS: Fibromyalgia, Exercise, Physiotherapy.

Fibromyalgia syndrome (FMS) is gaining increasing recognition among rheumatologists. Despite the failure to demonstrate consistent structural changes, the prognosis for resolution is poor with significant continuing morbidity. Ninety-seven per cent of patients continued to have symptoms after 1.5–6 yr, 60% worse and 26% better compared with presentation [1]. In a longer-term study over 10 yr all patients continued to have symptoms but overall fared better with 66% feeling a little or a lot better, only 7% feeling worse and 55% feeling well or very well in relation to fibromyalgia symptoms [2]. One of the few treatments found to be effective in randomized controlled studies is a graded aerobic exercise regimen [3–7]. However, these studies fail to show significant improvement in subjective pain levels, although improvements are seen in other parameters such as tenderness, patients' and physicians' global assessment, energy levels and work capacity. Long-term results are even more disappointing [5]. Two studies, both lacking a suitable randomized control group, have shown a beneficial effect of exercise and a formal group education programme on the Fibromyalgia Impact Questionnaire compared with pre-treatment values [8] and a non-randomized control group [9]. Many of these exercise regimens are labour intensive in terms of physiotherapist time but only have relatively modest beneficial effects. We therefore decided to compare two different approaches. The first one was our usual regime of a 1-h one-to-one session with a physiotherapist consisting of instruction in a graded aerobic exercise regimen, stretching and relaxation exercises, reinforced with written instructions on how to carry out these at home. The second consisted of 12 1-h supervised exercise classes held at weekly intervals with the same written instructions regarding home exercises. The two regimes used identical physiotherapist time.

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Patients and methods

The study protocol was approved by the Tayside Committee on Research Medical Ethics. Seventy-four patients who fulfilled the American College of Rheumatology's criteria for fibromyalgia [10] were recruited and allocated randomly to one of two treatment groups:

(1) Demonstration of aerobic exercises plus stretching and relaxation techniques with tailoring for the individual patient's needs and abilities by a physiotherapist on one occasion. Written advice was given and patients were instructed to continue and gradually increase these exercises at home (the single session group);

or

(2) Twelve weekly 1 h graded cardiovascular fitness classes plus stretching and relaxation techniques all supervised by a physiotherapist with written advice and encouragement to continue and increase these exercises at home (exercise class group).

In each group, exercises comprised a series of warming up and stretching exercises followed by a programme of graded circuit exercises consisting of step-ups, sitting to standing, skipping, jogging on the spot, alternate side bends, circling arms with increasing weights.

The patients' attendance record at the classes was recorded.

Before entry to the study, informed consent was obtained and the following baseline information was recorded:

(a) name, age, sex, duration of symptoms;
(b) visual analogue pain scale consisting of a 10 cm line on which patients recorded the degree of pain experienced in the previous week;
(c) total myalgic score—tenderness at the 18 tender points identified by Wolfe *et al.* [10] was measured using a dolorimeter and the sum of the forces required to produce pain was recorded;
(d) modified Stanford Health Assessment Questionnaire (HAQ) [11];
(e) hospital anxiety and depression questionnaire (HAD);
(f) number of nights per week in which difficulty with sleep was experienced;
(g) average number of hours slept each night over the previous 1 week;
(h) resting pulse rate.

A routine cardiovascular and respiratory examination including blood pressure was made and recorded at baseline.

The patients were allowed tricyclic antidepressants, analgesics and non-steroidal anti-inflammatory drugs as indicated by the physician. However, treatment had to remain stable for 1 month prior to entry to the study.

Assessments (b) to (h) plus patients' assessment of percentage of recommended home exercises carried out and patients' assessment of change in pain from baseline based on a 7-point score was repeated at 12, 24 and 48 weeks.

Statistical comparisons were carried out on an intention to treat basis both within the group and between groups using the appropriate non-parametric statistics. Subgroup analysis was carried out on a treatment received basis. The study was designed to achieve a power of 90% ($\alpha = 0.05$, $\beta = 0.1$) to demonstrate a change of 15 mm in the visual analogue pain score which we designated the primary outcome measure.

Results

Thirty-seven patients were randomized to the exercise classes and 37 to the single session. Fifteen of the 37 allocated to the classes attended at least nine (75%) classes whereas 35 of the 37 allocated to the single session attended the session. The results were broadly similar for both the intention to treat analysis and treatment received (defined as attending 9/12 classes or the single session) and therefore only the results of the intention to treat analysis are presented, except where the analyses differ in detail, in which case, the results from both are presented. Table 1 shows inter- and intra-group comparisons for the various parameters. The only significant differences between group comparisons were for the anxiety component of the HAD score (in favour of the class). These differences were stronger on the treatment completed analysis (Table 2). Although the HAQ score showed no difference between groups it did demonstrate a within-group deterioration in the single session group. A deterioration at 24 weeks in the total myalgic score was seen for the classes. Patients' assessment of change in pain from baseline showed no significant differences on a 7-point scale; median for both groups at 48 weeks was 5 ('a little better'). The continuation rate of exercises at home was low in each group. After 12 weeks, patients randomized to the classes were carrying out 72% of their home exercises and those randomized to the single session 50% (medians). By 48 weeks these figures had fallen to 10% and 20%, respectively.

Discussion

The results of this study are disappointing. Although multiple comparisons were carried out, improvement with the classes was seen only in measures of psychological well-being. In addition the classes failed to show the deterioration in functional status seen in the single session group. However, no improvement was seen in pain which is the presenting feature, and thus presumably the most important complaint of patients with fibromyalgia. No control group using no treatment was used. However, as both groups showed no significant improvements on within-group analysis in these parameters it can be surmised that neither was effective in improving pain or tenderness. Furthermore, only the improvement in the depression component of the HAD was maintained at 1 yr.

Several randomized controlled studies [3–7] have found intensive aerobic exercise regimens to be useful and aerobic exercise is now regarded as a standard treatment for fibromyalgia. The exact programmes used in these studies differed but were generally more intensive than that used by ourselves and some, in addition, incorporated an education programme. The measures of efficacy used differed between these various studies. Three of these studies showed an improvement in total myalgic score [3–5], two [4,5] showed an improvement in the number of tender points and one [5] showed an improvement in pain distribution. None of the studies showed a statistically significant improvement in the pain score. Wigers *et al.* [5] also showed an improvement in depression, lack of energy and work capacity. The two studies which did not contain randomized control groups [8,9] showed improvements in the Fibromyalgia

TABLE 1. Comparison of the effect of physiotherapy classes and a single session (both with home exercises) on measures of disease severity. Medians (25th–75th percentiles)

		Week 0	Week 12	Week 24	Week 48	Wilcoxon (0v12)	Wilcoxon (0v24)	Wilcoxon (0v48)
Visual analogue pain score (mm)	Class $n = 37$	62 (42–74)	64 (50–78)	68 (48–80)	72 (59–81)	NS	NS	NS
	Single session $n = 37$	63 (50–76)	67 (49–75)	70 (52–79)	67 (49–74)	NS	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
Total myalgic score (kg)	Class $n = 37$	34 (26–41)	34 (28–41)	31 (24–38)	33 (25–42)	NS	$P = 0.0117$[a]	NS
	Single session $n = 37$	34 (26–42)	31 (25–38)	35 (26–39)	30 (28–40)	NS	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
HAQ	Class $n = 37$	1 (0.75–1.62)	1 (0.84–1.4)	1.12 (0.87–1.69)	1 (0.81–1.7)	NS	NS	NS
	Single session $n = 37$	1.25 (0.87–1.5)	1.3 (0.87–2)	1.25 (0.87–2.06)	1.3 (1–1.75)	$P = 0.0138$	$P = 0.0143$	$P = 0.0047$
	Mann–Whitney	NS	NS	NS	NS			
HAD—anxiety	Class $n = 37$	9.5 (7.5–13.5)	8 (6–11.2)	10.5 (6.5–13)	8 (7–9)	NS	NS	NS
	Single session $n = 37$	11 (8.7–13.2)	10.5 (8–14.5)	11 (8–15.2)	10 (7.5–14.5)	NS	$P = 0.0268$	NS
	Mann–Whitney	NS	$P = 0.0432$	NS	NS			
HAD—depression	Class $n = 37$	9 (6.5–9)	9 (5.7–10)	10 (5–11)	7.5 (4–9)	NS	NS	NS
	Single session $n = 37$	11 (6.7–12)	10.5 (7–15)	11 (6.75–12.2)	10 (6.5–13)	$P = 0.027$	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
Resting pulse (beats/min)	Class $n = 37$	82 (73–88)	80 (68–84)	84 (72–85)	f83 (72–94)	NS	NS	NS
	Single session $n = 37$	80 (72–84)	84 (72–95)	82 (72–94)	77 (70–95)	NS	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
Number of nights/week poor sleep	Class $n = 37$	7 (4–7)	6.5 (1–7)	7 (4–7)	6.5 (3–7)	NS	NS	NS
	Single session $n = 37$	7 (4–7)	7 (3.5–7)	7 (3.7–7)	7 (6–7)	NS	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
Average hours sleep/night	Class $n = 37$	5 (4–6)	6 (4–6)	5 (4–6)	5 (4–6)	NS	NS	NS
	Single session $n = 37$	5 (3.7–6)	4.5 (4–6)	5 (4–6)	5 (4–6)	NS	NS	NS
	Mann–Whitney	NS	NS	NS	NS			
% home exercises performed (from direct questioning of patient)	Class $n = 37$		50 (10–82)	37 (10–65)	10 (0–57)			
	Single session $n = 37$		50 (7–71)	20 (0–55)	20 (0–57)			
	Mann–Whitney		NS	NS	NS			

[a]Deterioration.
Total myalgic score, sum of forces required to produce pain at each of the 18 ACR tender spots.
NS, not significant.

TABLE 2. Comparison of the effect of physiotherapy classes and a single session (both with home exercises) on HAD in the 'treatment completed' groups. Medians (25th–75th percentiles)

		Week 0	Week 12	Week 24	Week 48	Wilcoxon (0v12)	Wilcoxon (0v24)	Wilcoxon (0v48)
HAD—anxiety	Class $n = 15$	9 (5.5–13)	8 (6.5–10.2)	9 (6–11)	8 (6–11)	NS	NS	NS
	Single session $n = 35$	9 (8–13.7)	9 (8–14.2)	10.5 (8–15)	10 (7.2–14.7)	NS	NS	NS
	Mann–Whitney	NS	$P = 0.036$	NS	NS			
HAD—depression	Class $n = 15$	8 (5.2–9.7)	7 (5–9.2)	5 (3.2–9)	7 (4.2–9)	NS	NS	NS
	Single session $n = 35$	10 (6–12)	10 (7–14.2)	10.5 (6.5–12.5)	10 (6.2–13)	$P = 0.016$	$P = 0.049$	NS
	Mann–Whitney	NS	$P = 0.023$	$P = 0.018$	$P = 0.045$			

Impact Questionnaire; one of these [8] also showed improvement in the various measures of self-efficacy and the other [9] in tenderness count. The duration of the exercise classes in these studies was from 6 weeks to 6 months. Both ourselves and Wigers *et al.* [5] found that compliance with home exercises after the formal exercise programme was poor and in our study fewer than half the patients attended even 75% of the classes, although Burckhardt *et al.* [8], who also included an education programme, found that the majority continued to do their exercises.

Thus, although the exercise class in our study differed in intensity from that in the previous studies, our disappointing results with regard to the patients' perception of pain are similar to these previous studies, although our power calculations were based on a 15 mm improvement on the visual analogue pain score and it is possible that a smaller but real improvement might have occurred. We also found no difference between the groups in patients' perception of overall improvement. At 48 weeks patients in both groups felt some improvement. This may represent the natural history of fibromyalgia, an improvement in both groups resulting from regular contact with the research nurse or a desire to please.

The answer to our original question comparing the two exercise programmes must be that they did not differ with respect to our primary outcome measure of visual analogue pain score. Some differences were seen, primarily in psychological status, although these were modest and ill-sustained. From this study and a review of previous studies we must question the generally held view that aerobic exercise programmes are a major useful treatment for fibromyalgia. In the short term, improvement seems modest, useful long-term benefit has not been found and compliance is poor.

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