EXTENDED REPORT

Fibromyalgia: a randomised, controlled trial of a treatment programme based on self management

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Objective: To evaluate the efficacy of a treatment programme for patients with fibromyalgia (FM) based on self management, using pool exercises and education.
Methods: Randomised controlled trial with a 6 month follow up to evaluate an outpatient multidisciplinary programme; 164 patients with FM were allocated to an immediate 6 week programme (n = 84) or to a waiting list control group (n = 80). The main outcomes were changes in quality of life, functional consequences, patient satisfaction and pain, using a combination of patient questionnaires and clinical examinations. The questionnaires included the Fibromyalgia Impact Questionnaire (FIQ), Psychological General Well-Being (PGWB) index, regional pain score diagrams, and patient satisfaction measures.
Results: 61 participants in the treatment group and 68 controls completed the programme and 6 month follow up examinations. Six months after programme completion, significant improvements in quality of life and functional consequences of FM were seen in the treatment group as compared with the controls and as measured by scores on both the FIQ (total score p = 0.025; fatigue p = 0.003; depression p = 0.031) and PGWB (total score p = 0.032; anxiety p = 0.011; vitality p = 0.013,). All four major areas of patient satisfaction showed greater improvement in the treatment than the control groups; between-group differences were statistically significant for ''control of symptoms'', ''psychosocial factors'', and ''physical therapy'' No change in pain was seen.
Conclusion: A 6 week self management based programme of pool exercises and education can improve the quality of life of patients with FM and their satisfaction with treatment. These improvements are sustained for at least 6 months after programme completion.

The fibromyalgia (FM) syndrome is characterised by generalised musculoskeletal pain, a predictable pattern of ''tender points'' (TP), stiffness, fatigue, and disturbed sleep.[1] FM affects women about eight times more often than men.[2] Emotional distress is common in FM[3] and quality of life is impaired,[4 5] often more so than in other painful diseases such as rheumatoid arthritis.[6 7] Although there is no specific treatment, various management programmes have been proposed to deal with different aspects of the disease, particularly psychological distress, poor quality of life, functional impairments,[8–10] decreased muscle strength and endurance,[11] and low levels of physical fitness.[12]

The critical elements of successful self management programmes for FM include education about the syndrome and a well informed patient at the centre of the management team.[13] Such programmes emphasise communication and a combination of cognitive-behavioural techniques and physical training such as pool exercises which, together with walking, are well tolerated by patients with FM.[14–17] However, programmes emphasising exercise can have low volunteer rates,[18] a high number of drop outs,[10] or poor compliance due to increased pain after exercise.[19] Despite the substantial economic and human costs of FM, few randomised studies have evaluated such treatment programmes. There are no published studies on multidisciplinary programmes including pool exercises and education which enrolled a large number of patients and conducted follow up over a period of at least 6 months.

This study evaluated a multidisciplinary self management programme developed in consultation with a local FM association. The programme explicitly promoted self management strategies, combining pool exercises and education. It was suggested that the programme would improve the participants' quality of life and satisfaction with treatment, as well as decrease the functional and symptomatic consequences of FM, as compared with a control group.

MATERIALS AND METHODS

Subjects

Participants were volunteers from among patients with FM referred to the divisions of rheumatology and re-education at the Geneva University Hospital. Participation was proposed to 176 consecutive outpatients diagnosed with FM and living in the Geneva area. Recruitment was from November 1998 to September 2000 and follow up from June 1999 to April 2001. The major inclusion criteria were the American College of Rheumatology criteria for FM[1] and sufficient fluency in French to participate in group sessions. Exclusion criteria were the presence of specific medical disorders which required immediate treatment (for example, fractures, infectious diseases), prevented physical activity (for example, cardiovascular problems) or participation in swimming pool sessions (for example, skin diseases, allergy to chlorine). The protocol was approved by the local ethics committee and written informed consent was obtained from all participants.

Both the treatment and control groups were evaluated at baseline and at the 6 month follow up. The treatment group participated in a 6 week programme with re-evaluation 6 months after programme completion. The control group was offered the treatment programme after the 6 month follow up evaluation. The treatment and control groups

Abbreviations: FIQ, Fibromyalgia Impact Questionnaire; SF-36, Short Form-36; FM, fibromyalgia; PGWB, Psychological General Well-Being; RPS, regional pain score; TP, tender points

continued to receive their regular care, including physical therapy, drug treatment and, in some cases, psychotherapy.

Programme

The multidisciplinary programme consisted of 12 sessions, twice a week for 6 weeks. Attendance at ⩾10 sessions was considered full compliance with the programme; 3–9 as partial compliance, and <3 as withdrawal. Each session lasted 90 minutes (2×45 minutes) and was conducted in groups of 8–10 people. The programme included swimming pool sessions in 34°C water (8×45 minutes), relaxation exercises (4×45 minutes), low impact land based exercises (2×45 minutes), sessions on activities of daily living (2×90 minutes), and education-discussion sessions (6×45 minutes). Pool and land based sessions were led by a physiotherapist. Sessions on ''activities of daily living'' were led by an occupational therapist and examined questions on everyday life from the weekly diaries of the participants. The education-discussion sessions were held with the entire management team, including a rheumatologist and a psychologist, and dealt with many aspects of FM such as current scientific knowledge, associated conditions, symptoms, modulating factors, and personal relationships. One of these sessions offered participants the opportunity to invite a support person.

Throughout the programme, self management was explicitly promoted: participants were instructed to find their own pace when exercising and in their daily activities. The pool sessions and the land based exercises (relaxation and low impact) mainly aimed at breaking the inactivity pattern of patients with FM but also at helping them to apply relaxation techniques. The activities of daily living sessions focused on helping the participants to plan their activities in order to minimise fatigue and pain, and thus eventually to increase their level of activity. The education-discussion sessions provided further opportunities to discuss the difficulties of everyday life and share possible solutions.

Patient examination

Baseline and follow up examinations were performed by experienced rheumatologists and physiatrists, according to the protocol described by Wolfe *et al*.[1] The number of TP and the myalgic score were recorded. Participants were interviewed by the examining physician using a standardised questionnaire to record sociodemographic characteristics, date of symptom onset, duration of symptoms, concurrent health problems, and use of healthcare services in the previous 6 months—that is, number of visits to a general practitioner, a specialist (rheumatologist or physiatrist), a psychiatrist or psychologist, and/or a physical therapist. Physical treatments included active (for example, exercises) and passive (for example, massage) modalities. The physician rated his or her clinical global impression on a five point scale (1 = best).

Self administered questionnaire

At the time of the baseline and follow up medical evaluations subjects were asked to bring a self administered questionnaire which had been mailed to them beforehand. This questionnaire included elements from five standard instruments. Quality of life was evaluated using questions from the validated French version of the Psychological General Well-Being (PGWB) index[20–22] and the validated French version of the Short Form-36 (SF-36),[23] a non-specific health and functional status questionnaire. The PGWB instrument has six subscales for a total of 22 items measuring ''anxiety'', ''depression'', ''general health'', ''positive wellbeing'', ''self control'', and ''vitality''. Each item is scored from 0 to 5, providing a total score of between 0 and 110, with higher values indicating more positive responses. The SF-36 subscales for ''general health'', ''physical functioning'', ''role-physical'', and ''social functioning'' were used. Scores for each subscale range from 0 to 100 (best). The ''role-emotional'', ''mental health'', and ''vitality'' subscales were not included because of the overlap with the PGWB.

To evaluate the functional and symptomatic consequences of FM the questionnaire included elements of the Fibromyalgia Impact Questionnaire (FIQ),[24] which has 10 subscales to assess ''physical function'', ''number of days feeling bad'', ''work missed'', ''job ability'', ''pain'', ''fatigue'', ''morning tiredness'', ''stiffness'', ''anxiety'', and ''depression''. Higher scores indicate a negative impact. To assess pain, the regional pain score (RPS) was included, with participants asked to indicate on a body drawing their level of pain in each of 21 regions (range: 0 = ''no pain'' to 5 = ''unbearable pain''), providing a total score of between 0 and 105. The RPS has been validated with patients with FM.[25 26] Patient satisfaction with the intervention was investigated using items generated by Potts and Silverman.[27] Patients were asked to rate on Likert-type scales the importance and satisfaction with FM treatment in four major areas: physical therapy, symptom control, psychosocial factors, and information. For each item, response options ranged from 0 to 5, with a higher value indicating a more positive response. At the time of the follow up evaluation, to appraise the adherence to the emphasis put on breaking the inactivity pattern during the programme, participants were asked whether they had continued swimming pool exercises regularly, had resumed an activity they had given up because of their symptoms, or engaged in a new activity.

Power calculations

Based on compliance data from a trial conducted in Geneva on electroacupuncture and FM,[21] and attrition rates in similar studies, it was calculated that two groups of 84 patients (treatment *v* control patients) at baseline were needed to maintain a statistical power of 80% ($\alpha = 5\%$ and $\beta = 20\%$) to detect a between-group difference of half a standard deviation on any continuous variable.

Randomisation

After baseline medical evaluation, participants were randomly allocated to a treatment group or a control group. The assignment was performed in blocks of 20, split into treatment programme (n = 10) or control (n = 10). Randomisation was made by means of an electronic numbers generator (SPSS). An independent person who was not responsible for determining the participants eligibility provided sequentially numbered, sealed, and opaque envelopes.

Statistical methods

Demographic data were compared using χ^2 tests for categorical data and a *t* test for continuous data. Study outcomes (difference scores of baseline value minus follow up value) were evaluated using the non-parametric Wilcoxon signed rank test (two tailed) for paired data. Differences between the treatment and the control groups were evaluated using the Mann-Whitney test.

RESULTS

Of the 176 consecutive patients who volunteered to participate in this study, eight were excluded for medical reasons (cardiovascular problems or allergy to chlorine) and four withdrew because of other commitments. After medical evaluation, 164 participants were randomly allocated to the treatment (n = 84) or the control group (n = 80). Sixty one patients (73%) in the treatment group and 68 (85%) in the control group completed the 6 month follow up and were

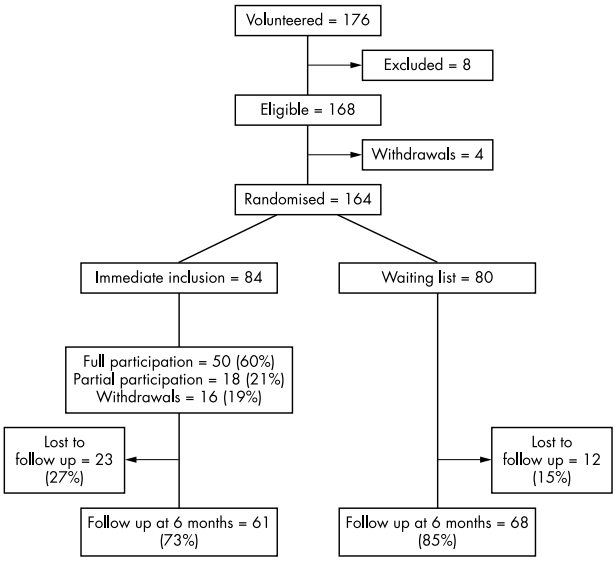

Figure 1 Flow diagram of the participants in the randomised trial.

included in the final analyses. Two participants in the treatment group explicitly cited an increase in pain as the reason for dropping out. Figure 1 presents the flow diagram of the trial. This figure also shows that full participation was obtained in 60% of the patients. The chart of attendance showed no specific bias against any particular session.

Comparison of the sociodemographic variables and duration of FM symptoms showed no statistically significant differences between the treatment and control groups (table 1). The majority of the participants in both groups were female (93%). The mean (SD) age was 48.9 (9.7) and 49.8 (9.8) years in the treatment and control groups, respectively. Most of the patients were married (65%), 46% had completed compulsory school, and 37% were Swiss. Seventeen per cent of patients in the treatment group and 16% of controls were working while 43% were receiving a disability pension. The mean duration of symptoms was 8.4 years (median 5.7) in the treatment group and 9.5 years (median 6.1) in the control group. There were no differences in the use of medical, physical, or psychological treatments at baseline between the treatment and control groups. No differences were seen in sociodemographic characteristics or in any of the investigated dimensions at baseline between the subjects lost to follow up and those who completed the follow up examination in either group.

Table 1 Sociodemographic characteristics of patients with FM by treatment group

Characteristics	Treatment No (%)	Control No (%)	p
Sex			
Male	6 (7)	6 (8)	NS
Female	78 (93)	74 (93)	
Age (years)			
⩽40	20 (24)	16 (20)	NS
41–50	32 (38)	31 (39)	
51–60	23 (27)	20 (25)	
>60	9 (10.7)	13 (16)	
Mean (SD)	48.9 (9.7)	49.8 (9.8)	NS
Cultural origin			
Switzerland	33 (39)	27 (34)	NS
France	6 (7)	7 (9)	
Italy	4 (5)	10 (13)	
Spain	8 (10)	7 (9)	
Portugal	19 (23)	13 (16)	
Other	14 (17)	16 (20)	
Marital status			
Single	6 (7)	5 (6)	NS
Married	58 (69)	48 (60)	
Divorced	16 (19)	25 (31)	
Widow	4 (5)	2 (3)	
Education (completed)			
Compulsory school	39 (46)	37 (46)	NS
Diploma	39 (46)	35 (44)	
University degree	6 (7)	8 (10)	
Employment status			
Employed	14 (17)	13 (16)	NS
Not working/retired	12 (14)	20 (25)	
Sick leave	19 (23)	15 (19)	
Disability pension	39 (46)	32 (40)	
Duration of symptoms (years)			
Mean (SD)	8.4 (8.2)	9.5 (9.6)	NS
Total	84	80	

Table 2 compares the ''quality of life'' measurements at baseline and follow up, as reflected in the scores of the PGWB and the SF-36 items in the self administered questionnaire. The treatment group showed a significant improvement in the PGWB ''anxiety'' ($p = 0.021$), ''vitality'' ($p = 0.013$), and total scores ($p = 0.016$). The treatment group also showed improvement in each of the other PGWB scores and in all of the SF-36 scores, though these results were not statistically significant. No significant differences were seen in the baseline and follow up values in the control group; however, four of the six PGWB scores and two of the four SF-36 scores remained the same or deteriorated. In the between-group analysis the treatment group showed a significant improvement in the PGWB ''anxiety'' ($p = 0.011$), ''vitality'' ($p = 0.013$), and total scores ($p = 0.032$).

Table 3 compares the functional and symptomatic consequences of FM at baseline and the 6 month follow up as measured by the number of TP, the physician's clinical rating, the RPS, and the FIQ scores within and between the treatment and control groups. In the treatment group significant improvements were seen in the FIQ total score ($p<0.001$), and the subscales for ''fatigue'' ($p = 0.001$), ''morning tiredness'' ($p = 0.006$) and ''anxiety'' ($p = 0.002$). No improvements were seen in the control group, and in that group the FIQ subscale for ''pain'' showed a significant deterioration ($p = 0.017$). No changes were seen in the number of TP, the myalgic score, and the RPS in either group. No change was seen in the physician's clinical rating in the treatment group, but this rating showed a significant deterioration in the control group ($p<0.05$). A comparison of the groups showed significant improvements in the treatment group compared with the control group in the FIQ total score ($p = 0.025$) and the subscales for ''pain'' ($p = 0.025$), ''fatigue'' ($p = 0.003$), and ''depression'' ($p = 0.031$). Although there were no between-group differences in the use of medical and psychological services at the 6 month follow up, the treatment group used significantly less ($p = 0.038$) physical therapy services: the mean (SD) number of physical therapy visits dropped from 15.1 (15) to 7.6 (11), ($p<0.05$) in the treatment group, whereas it decreased only from 12.1 (11.9) to 10.4 (14.9) in the control group.

Table 4 shows the status of participant satisfaction in the programme. All four major areas of patient satisfaction showed greater improvement in the treatment than in the control groups; between-group differences were statistically significant for ''physical therapy'', ''symptom control'', and ''psychosocial factors''. The treatment group showed a significant improvement in all four of the measurements in the area of ''physical therapy'' (increased ability to do activities $p = 0.017$, exercise instruction $p = 0.011$, instruction in relaxation $p = 0.000$, encouragement to practice self care $p = 0.030$). Similarly, the treatment group had a greater

Table 2 Comparison of baseline and 6 month results of quality of life questionnaires by treatment group

	Treatment						Control							
	Baseline		6 Months after		Difference		Baseline		6 Months after		Difference		Difference between groups	
Questionnaire	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	p
PGWB†														
Total score (0–110)	45.9	(17.6)	51.1	(19.4)	−5.2*	(14.1)	44.0	(19.3)	43.8	(20.9)	0.2	(11.6)	−5.4	**0.032**
Anxiety	11.4	(5.3)	13.0	(6.2)	−1.6*	(5.1)	10.8	(5.4)	10.3	(5.6)	0.5	(4.2)	−2.1	**0.011**
Depression	8.3	(3.4)	9.0	(3.6)	−0.7	(3.1)	7.6	(4.0)	7.7	(4.2)	−0.1	(3.0)	−0.6	0.126
General health	5.3	(1.9)	5.8	(2.1)	−0.5	(2.2)	5.0	(2.3)	5.4	(2.3)	−0.4	(1.6)	−0.1	0.849
Positive wellbeing	8.0	(4.1)	8.9	(4.3)	−0.9	(3.0)	7.5	(4.0)	7.5	(4.6)	0.0	(2.9)	−0.9	0.129
Self control	6.9	(3.4)	7.4	(3.3)	−0.5	(2.9)	6.4	(3.4)	6.4	(3.3)	0.0	(2.6)	−0.5	0.298
Vitality	6.0	(3.7)	6.9	(3.3)	−0.9*	(2.4)	6.7	(3.4)	6.5	(3.7)	0.2	(2.4)	−1.1	**0.013**
SF-36†														
Physical functioning	41.8	(18.1)	42.2	(19.8)	−0.4	(15.8)	46.8	(19.4)	43.9	(19.6)	2.9	(17.0)	−3.3	0.293
Role-physical	14.6	(27.3)	21.5	(29.0)	−6.9	(36.5)	13.6	(27.5)	16.5	(30.1)	−2.9	(25.7)	−3.9	0.093
General health	32.6	(16.5)	34.3	(17.3)	−1.7	(11.0)	29.8	(18.5)	28.8	(18.9)	1.0	(13.3)	−2.7	0.241
Social functioning	35.3	(21.6)	41.2	(21.6)	−5.9	(22.4)	32.5	(20.3)	34.2	(21.0)	−1.7	(19.1)	−4.2	0.238

*p<0.05; † Higher scores indicate more positive responses.

improvement than the control group in the four measures of satisfaction with ''symptom control'', with the between-group improvement being significant for pain relief ($p = 0.01$) and reduced stiffness ($p = 0.003$). The treatment group also recorded a greater improvement than the controls in eight of the nine participant satisfaction measures in the areas of ''psychosocial factors'' and ''information''. Three of these improvements were significant—namely, stress reduction ($p = 0.000$), improved memory and attention ($p = 0.004$), and information on cause of condition ($p = 0.007$).

To evaluate the potential impact of the participants who had been lost to follow up, the analyses were repeated using all participants and assigning no change to the baseline and follow up values attributed to those who had been lost from either the treatment or the control groups. The statistically significant between-group differences were maintained for all scores except the PGWB total score.

At the time of the follow up evaluation, 41/61 (67%) patients in the treatment group were continuing swimming pool exercises regularly. Resuming an activity given up because of the symptoms was mentioned in 23% of the patients in the treatment group *v* 9% in the control group ($p = 0.058$), and engaging in a new activity in 25% *v* 9% ($p = 0.028$).

DISCUSSION

This study found that patients with FM enrolled in a 6 week self management based programme which included warm water activities and education had significant improvements in both quality of life and the functional consequences of FM as compared with a control group. The treatment group also showed significant improvements in patient satisfaction, particularly when compared with the controls. These improvements were sustained 6 months after completion of the programme. Though similar self management programmes have for some time been promoted as an important part of FM treatment, this randomised control study reports the results of a programme combining warm water activities and education with sufficient patient numbers and follow up to have the power to begin critically evaluating these treatments.

Table 3 Comparison of baseline and 6 month results of symptomatic and functional consequences of FM by treatment group

	Treatment						Control							
	Baseline		6 Months after		Difference		Baseline		6 Months after		Difference		Difference between groups	
Consequences	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	p
Physician's evaluation of pain														
Tender points (n)	15.4	(2.3)	15.0	(3.6)	0.4	(3.1)	15.8	(2.8)	16.2	(2.7)	−0.4	(2.3)	0.8	0.216
Tender points >1 (n)	10.5	(4.8)	9.9	(4.9)	0.6	(4.0)	10.9	(4.4)	11.4	(4.8)	−0.5	(5.2)	0.1	0.282
Myalgic score	29.9	(9.1)	29.5	(11.5)	0.4	(8.0)	30.6	(9.1)	31.8	(10.2)	−1.2	(9.2)	1.5	0.461
Physician's score†	2.8	(1.0)	2.8	(1.0)	0.0	(1.3)	2.8	(1.0)	3.1	(0.8)	−0.3*	(0.8)	0.4	0.052
Regional pain score‡ (0–105)	63.9	(18.0)	62.6	(20.7)	1.3	(14.2)	67.0	(15.7)	68.4	(15.1)	−1.4	(11.6)	2.7	0.391
Functional and symptomatic consequences of FM (FIQ‡)														
Total score	5.5	(1.3)	4.9	(1.4)	0.6***	(1.2)	5.6	(1.6)	5.5	(1.5)	0.1	(1.2)	0.7	**0.025**
Physical function	4.2	(2.0)	4.3	(2.1)	−0.1	(1.8)	4.5	(2.2)	4.8	(2.5)	−0.3	(1.8)	0.2	0.584
Feel bad	8.3	(2.3)	8.2	(2.6)	0.1	(3.3)	8.0	(2.8)	7.9	(2.5)	0.1	(2.6)	0.0	0.697
Work missed	1.6	(4.1)	3.3	(2.7)	−1.7	(4.6)	2.5	(3.9)	3.1	(4.7)	−0.6	(5.5)	−1.1	0.713
Job ability	6.1	(2.5)	4.7	(2.5)	1.4	(2.4)	6.7	(2.5)	4.7	(3.5)	2.0	(3.2)	−0.6	0.897
Pain	6.3	(1.9)	6.1	(2.1)	0.2	(2.0)	6.0	(2.1)	6.6	(2.1)	−0.6*	(2.2)	0.8	**0.025**
Fatigue	7.5	(1.7)	6.5	(2.3)	1.0**	(2.2)	7.4	(2.4)	7.7	(1.9)	−0.3	(2.3)	1.3	**0.003**
Morning tiredness	7.7	(2.0)	6.8	(2.3)	0.9**	(2.2)	7.6	(2.5)	7.5	(2.2)	0.1	(2.1)	0.8	0.056
Stiffness	6.6	(2.7)	6.3	(2.0)	0.3	(2.2)	6.5	(2.7)	6.8	(2.6)	−0.3	(2.6)	0.6	0.147
Anxiety	6.4	(2.6)	5.1	(2.9)	1.3**	(3.1)	7.1	(2.7)	6.7	(3.0)	0.4	(2.0)	0.9	0.078
Depression	5.5	(3.1)	4.6	(3.1)	0.9	(2.9)	5.9	(3.5)	6.1	(3.4)	−0.2	(2.5)	1.1	**0.031**

*p<0.05, **p<0.01, ***p<0.001; †1 = best, 5 = worst; ‡lower values indicate more positive responses.

Table 4 Comparison of baseline and 6 month results of patient's satisfaction questionnaire by treatment group

	Treatment						Control						Difference between groups	
	Baseline		6 Months after		Difference		Baseline		6 Months after		Difference			
Results	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	p
Control of symptoms	**7.8**	**(3.9)**	**10.2**	**(5.2)**	**−2.4***	**(5.4)**	**7.1**	**(4.5)**	**7.3**	**(4.8)**	**−0.2**	**(4.0)**	**−2.2**	**0.007**
Pain relief	2.0	(1.1)	2.7	(1.5)	−0.7*	(1.5)	1.8	(1.3)	1.9	(1.4)	−0.1	(1.2)	−0.6	**0.010**
Reduced fatigue	1.9	(1.3)	2.4	(1.4)	−0.5*	(1.7)	1.5	(1.4)	1.6	(1.4)	−0.1	(1.4)	−0.4	0.195
Improved sleep	2.2	(1.4)	2.6	(1.3)	−0.4	(1.7)	2.1	(1.3)	2.1	(1.5)	0.0	(1.3)	−0.4	0.182
Reduced stiffness	1.6	(1.3)	2.5	(1.5)	−0.9*	(1.8)	1.7	(1.4)	1.7	(1.3)	0.0	(1.3)	−0.9	**0.003**
Psychosocial factors	**9.9**	**(5.0)**	**14.7**	**(5.3)**	**−4.8****	**(5.9)**	**10.1**	**(5.2)**	**11.3**	**(5.7)**	**−1.2**	**(5.3)**	**−3.6**	**0.005**
Discussion of ways to reduce stress	2.1	(1.4)	3.3	(1.1)	−1.2**	(1.4)	2.2	(1.4)	2.2	(1.5)	0.0	(1.3)	−1.2	**0.000**
Reduced depression	2.5	(1.4)	2.9	(1.3)	−0.4	(1.6)	2.6	(1.3)	2.4	(1.7)	0.2	(1.6)	−0.6	0.065
Reduced anxiety	2.3	(1.5)	2.9	(1.2)	−0.6*	(1.5)	2.1	(1.5)	2.4	(1.5)	−0.3	(1.5)	−0.3	0.265
Improved memory and attention	1.2	(1.3)	2.5	(1.4)	−1.3**	(1.7)	1.5	(1.5)	1.9	(1.5)	−0.4*	(1.5)	−0.9	**0.004**
Inclusion of family in physician visits	2.3	(1.7)	3.4	(1.4)	−1.1**	(1.9)	1.9	(1.7)	2.8	(1.6)	−0.9*	(2.0)	−0.2	0.407
Information	**10.4**	**(4.0)**	**12.1**	**(4.2)**	**−1.7***	**(4.7)**	**9.7**	**(4.4)**	**10.2**	**(4.9)**	**−0.5**	**(4.5)**	**−1.2**	**0.129**
On prognosis	2.7	(1.3)	3.3	(1.3)	−0.7*	(1.6)	2.3	(1.5)	2.6	(1.5)	−0.3	(1.6)	−0.4	0.279
On cause of condition	2.8	(1.3)	3.6	(1.2)	−0.8*	(1.6)	2.7	(1.5)	2.8	(1.5)	−0.1	(1.6)	−0.7	**0.007**
On diagnostic techniques	2.2	(1.4)	2.6	(1.3)	−0.4	(1.6)	2.1	(1.6)	2.2	(1.6)	−0.1	(1.6)	−0.3	0.317
On drug side effects	2.7	(1.3)	2.6	(1.4)	0.1	(1.9)	2.5	(1.5)	2.6	(1.6)	−0.1	(1.7)	0.2	0.647
Physical therapy	**8.4**	**(4.1)**	**12.7**	**(4.6)**	**−4.3****	**4.9**	**8.6**	**(4.2)**	**9.2**	**(4.9)**	**−0.6**	**(4.7)**	**−3.7**	**0.000**
Increased ability to do activities	1.8	(1.2)	2.8	(1.4)	−1.0**	(1.5)	1.9	(1.5)	2.1	(1.4)	−0.2	(1.7)	−0.8	**0.017**
Exercise instruction	2.3	(1.6)	3.3	(1.4)	−1.0*	(2.1)	1.9	(1.5)	2.1	(1.6)	−0.2	(1.6)	−0.7	**0.011**
Instruction in relaxation	1.8	(1.6)	3.3	(1.3)	−1.5**	(1.8)	2.1	(1.4)	2.3	(1.5)	−0.2	(1.4)	−1.3	**0.000**
Encouragement to practice self care	2.6	(1.3)	3.4	(1.4)	−0.8*	(1.6)	2.6	(1.5)	2.7	(1.5)	−0.1	(1.7)	−0.7	**0.030**
Total score	**36.8**	**(12.5)**	**49.5**	**(17.8)**	**−12.7****	**(16.6)**	**35.2**	**(14.5)**	**36.9**	**(17.5)**	**−1.7**	**(13.8)**	**−11.0**	**0.000**

*p<0.05, **p<0.001; Scores range: 0–5, where 5 is best.

Although a number of other studies have recently shown an immediate benefit from FM management programmes that included warm water activities,[28–31] only two included a follow up evaluation, and only one had a no-intervention control group. In the latter, which allocated 48 patients to either 10 days of balneotherapy or a control group, Buskila *et al* showed a sustained benefit at 3 months for self assessed pain, fatigue, stiffness, and anxiety.[30] In the other study, which randomly allocated 34 patients to a pool or land based 20 week exercise programme, Jentoft *et al* found a benefit at 6 months in walking time and self assessed fatigue and stiffness in both groups.[31] The pool based group also showed improvements in self assessed pain, anxiety, and depression. The sex, age,[16 28 29] and symptom duration[29 30] of the participants in these studies were comparable to those of the patients evaluated here, though it is difficult to compare employment status owing to differences in coding for this variable.

The nature, direction, and magnitude of the findings of this study are consistent with the design of this self management programme, its various elements, and scientific publications on the treatment of patients with FM. For example, the improvements that were seen in quality of life are consistent with the development of better coping skills through this treatment programme. Throughout the programme, participants were instructed to find their own pace, when exercising and in their daily activities, with the explicit aim of promoting self management. That the treatment group also experienced substantially less fatigue and morning tiredness at 6 months is in keeping with the aims of the sessions on ''activities of daily living'' and physical training, as these had been specifically designed to deal with these problems. The pool sessions had been developed to break the characteristic inactivity pattern of patients with FM, whereas the activities of daily living sessions provided insight into the planning of such activities and the consequences of this planning. The improvements in the ''anxiety'', ''vitality'', and ''depression'' subscales of the FIQ and PGWB may demonstrate the value of providing sufficient opportunity for patients with FM to discuss the difficulties of their everyday life with other patients and various health professionals. Finally, the fact that the treatment group consistently reported greater satisfaction with their therapy than the control group reaffirms the value and potential impact of multidisciplinary management programmes that bring a range of expertise and individual attention to the challenges and problems these people experience, while doing so in a group setting that promotes their continued participation and interest.

Though the findings of this study offer encouragement in the management of patients with FM, the limitations of its design and outcomes should be recognised. Most notable is the common challenge of maintaining ''blinding'' in any behavioural and physical intervention study,[29 32] often because of the enthusiasm of participants to disclose their experience to examiners. In this study, coding of the baseline and follow up self administered questionnaires was blinded, however, as was the baseline medical evaluation conducted before randomisation. Nevertheless, it was not possible to ensure that the follow up medical evaluation at 6 months was blind. Compliance with the intervention was defined as ''attending the sessions''; considering the aim of the intervention—that is, to increase self management, actual compliance would be best evaluated as ''applying the instructions at the end of the study period''. However, the design of this study did not allow for a valid assessment of these aspects of compliance. Although there was some loss of follow up, the study completion rate of 79% was still high and the same as that seen in a 3 week trial on electroacupuncture and FM[21] that was conducted in the same rheumatology unit. The higher drop out rate among the treatment group than controls (27% *v* 15%) may thus have resulted from a number of factors other than chance, including a failure of the programme to meet early expectations and/or increased pain.

These results also indicate that even though the local FM association was interested in this programme and was involved in the preliminary discussions, there may be a substantial difference between meeting a group's request and meeting individual expectations. The lack of information on the end points for the drop outs did not allow us to perform the classic intention to treat analysis. The continuous nature of the variables makes it difficult to assign a quantitative value to the missing data. For this reason we analysed the data using an approach close to the per-protocol analysis—that is, using only the cases for which there was information at the end of the follow up. This approach may have led to an overestimate of the effects of the treatment, as the patients who completed the follow up may be those who presented the best response. However, when conservatively assuming zero changes to all the drop outs, we obtained the same results, only decreasing statistical power.

A major problem in multidisciplinary interventions is that classical outcome measures may underestimate the benefits of the intervention. Using individual defined aims has been suggested as a more sensitive tool for evaluating the effectiveness of an intervention.[33] This has been demonstrated in rheumatoid arthritis using the McMaster Toronto Arthritis patient preference questionnaire (MACTAR).[34 35] Such instruments should be tested with patients with FM as a means to gain further insight into patients' needs and expectations. Investigating these aspects may perhaps also explain the apparent discrepancies in the results—for example, the good effect on function in the satisfaction questionnaire compared with the absence of effect on physical function in SF-36 and FIQ, which show that satisfaction may not be automatically linked to actual performance. Patients' expectations and perception of their condition and its treatment may also affect their adherence to attendance at meetings and the withdrawal rate. These expectations and beliefs are related to the patients' understanding and experience of FM, and to the cost-benefit analysis that they may do when they are prescribed a treatment.[5 27] One of the difficulties in obtaining patients' adherence may be a level of expectations which can hardly be matched—in a condition for which there is at present no specific treatment—and thus causes a possibly important imbalance in the cost-benefit analysis. Finally, although the French version of most of the instruments used to measure the chosen outcomes had been validated in an FM population, the questions used to measure patient satisfaction had not yet undergone such validation.

There are also some limitations to the expected impact and generalisability of this programme to other patients with FM. Although there were substantial improvements in most measures of quality of life, functional consequences of FM, and patient satisfaction with treatment, many of the follow up scores were still low compared with non-FM populations. For example, the PGWB total score in the general population is as high as 105,[36] whereas it reached only 51.1 in this treatment group. Similarly, the SF-36 scores studied, which are expected to range from 71 to 84*, ranged from 21.5 to 42.2 at follow up in the treatment group. Although these values are comparable to those in other FM studies,[22 26 29] they underline the emotional distress, functional impairments, and poor quality of life that patients with FM experience.[37 38] In this regard, it would have been of interest to compare the ''vitality'' subscales of the PGWB and of the SF-36, as this subscale yielded significant differences before and after treatment and between-group differences. However, the overlap of both questionnaires was a matter of concern, especially for the psychological dimensions; when dealing with a group with specific chronic pain addressing psychological aspects is often perceived as a possible delegitimisation of their pain and suffering and/or as a denial of the somatic aspects of their complaint. The mean duration of symptoms in our group was high and this may account for the relatively small treatment effects 6 months after the programme. Such a programme may be more successful at the beginning of the symptoms; however, there were not enough patients with early FM to carry out post hoc subgroup analysis. Also, this study did not find substantial improvement in pain, whether self assessed or in the medical evaluation. Although the comparison of the FIQ subscale for pain showed a statistically significant difference in favour of the treatment group, this difference was largely due to a deterioration in the control group. Possibly, however, the intervention prevented an increase in pain in the treatment group. An alternative explanation might be that being randomised in a waiting list group may cause disappointment and a possible worsening of pain. This observation raises the question of the patients' expectations and of the difficulties in circumventing the possible drawbacks of using a waiting list as a control group. A study on the association of patients' expectations from a specific treatment with improved functional outcome showed that patients' expectations may influence clinical outcome independently of the treatment itself.[39] Using a waiting list avoids the effects of randomisation into a group that does not correspond with the patient's expectations but does not avoid the effects of having to wait for a treatment that may be helpful. Another limitation is that like other FM programmes that are based on self management, the addition of multiple interventions[13] to pool activities makes it difficult to evaluate the contribution of each element. Yet, no single treatment has been shown to have more than a limited benefit in patients with FM, in part because no single causative factor has been identified.[32 40] Finally, although this trial was conducted in a university setting which enabled the study, the outpatient programme itself did not require this type of setting.

Despite the limitations of this study it demonstrates that sufficient numbers of patients with FM can be enrolled in randomised control trials of treatment programmes that include complex behavioural and physical interventions. Given the substantial economic and human costs of this disease, as well as the increasing incidence and/or recognition of this condition in many areas, such studies are increasingly important. Future studies should not only enrol enough patients to ensure sufficient power of the findings but also consider the need to extend the follow up period for such studies to include at least a full 12 month period. The design, logistics, and funding of such work will itself be a challenge.

CONCLUSIONS

This study reports a large randomised controlled trial, with a 6 month follow up, of a multidisciplinary self management based programme for patients with FM. It found that a 6 week treatment programme, which combined physical activity, education, promotion of self management strategies, and development of coping skills, resulted in statistically significant improvement in quality of life, functional consequences of FM, and patient satisfaction with treatment. Furthermore, these improvements were sustained for at least 6 months after the programme completion, particularly for factors such as fatigue, depression, anxiety, and vitality.

This study shows that a mildly intensive programme of relatively short duration can help patients with FM, for whom there is no specific treatment. Substantial additional

*Richard JL, Bouzourène K, Gallant S, Ricciardi P, Sudre P, Iten A, Burnand B. Validation et normes du SF-36 dans la population du canton de Vaud. Lausanne: Institut universitaire de médecine sociale et préventive, 2000.

work is needed, with larger study groups and longer follow up periods, to examine further the underlying mechanisms for the improvements seen here. Such work may provide further insights into the crucial elements of these multidisciplinary programmes, as well as the minimum duration and intensity necessary to achieve sustained improvements.

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