

Pool Exercise Combined with an Education Program for Patients with Fibromyalgia Syndrome. A Prospective, Randomized Study

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ABSTRACT. *Objective.* To evaluate the effects of 6 months of pool exercise combined with a 6 session education program for patients with fibromyalgia syndrome (FM).

Methods. The study population comprised 58 patients, randomized to a treatment or a control group. Patients were instructed to match the pool exercises to their threshold of pain and fatigue. The education focused on strategies for coping with symptoms and encouragement of physical activity. The primary outcome measurements were the total score of the Fibromyalgia Impact Questionnaire (FIQ) and the 6 min walk test, recorded at study start and after 6 mo. Several other tests and instruments assessing functional limitations, severity of symptoms, disabilities, and quality of life were also applied. *Results.* Significant differences between the treatment group and the control group were found for the FIQ total score ($p = 0.017$) and the 6 min walk test ($p < 0.0001$). Significant differences were also found for physical function, grip strength, pain severity, social functioning, psychological distress, and quality of life.

Conclusion. The results suggest that a 6 month program of exercises in a temperate pool combined with education will improve the consequences of FM. (J Rheumatol 2000;27:2473-81)

Key Indexing Terms:

FIBROMYALGIA

PATIENT EDUCATION

POOL EXERCISE

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SF-36

Fibromyalgia syndrome (FM) is characterized by long lasting widespread pain, stiffness, and fatigue¹. Other symptoms frequently reported are disturbed sleep, headache, numbness, and irritable bowel², as well as anxiety, depression³, and a higher degree of stress than in healthy individuals⁴. Muscular performance of patients with FM has been found to be impaired compared to healthy individuals^{5,7}, and patients perceive disabilities in many basic activities of daily life, such as walking, working with their arms in elevated positions, lifting objects, and so on⁸⁻⁹.

The consequences of FM can be studied on different levels, such as the impairment level, e.g., intensity of pain or fatigue, the level of functional limitations as measured by standardized functional tests, the level of perceived disability, and psychological distress. Since no causal treatment for FM

is available, interest in treatments aiming at promotion of health, self-management of the symptoms, and improvement of physical function has increased. Studies focusing on physical training have shown improved aerobic fitness^{10,11}, increased grip strength¹², and increased work capacity¹³ in patients with FM. Patient education programs have indicated improvements in self-efficacy¹⁴ and pain coping¹⁵. In Sweden, patients with musculoskeletal disorders are often referred for exercises in a temperate pool, either as a single treatment modality or in combination with other treatments. Evaluations of the effects of pool training in patient populations or healthy individuals are scarce, but a few reports have been published^{16,19}. Positive effects on cardiorespiratory function and endurance of shoulder muscles have been found in older healthy adults after 12 weeks of pool training¹⁶. Improved aerobic capacity and increased muscle strength in the knee extensors were found for patients with rheumatoid arthritis (RA) who exercised twice a week for 2 months¹⁷. In another controlled study, an increased activity level was found in patients with RA who exercised once a week for 4 years¹⁸. A recent controlled study of 6 weeks' pool training and education for patients with FM indicated improvements in walking ability, well being, and fatigue¹⁹. The followup study also indicated improvements in anxiety, depression, self-efficacy, and knowledge of FM¹⁹. However, to our knowledge, no controlled studies of a longer training period have been published. We hypothesized that 6 months of training in a temperate pool combined with a 6 session patient education program

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would improve the consequences of FM. A disorder-specific instrument measuring consequences of FM and a measure of walking ability were chosen as the primary outcome measures.

MATERIALS AND METHODS

Patients. Patients were recruited from primary health care and rheumatology clinics in the Goteborg region that had been contacted by mail and invited to refer patients with FM. Sixty-nine women with FM who fulfilled the inclusion and exclusion criteria were included. The criteria for inclusion were: women with a diagnosis of FM and fulfillment of the American College of Rheumatology (ACR) 1990 criteria for FM¹. Criteria for exclusion were other rheumatic diseases, other severe somatic or psychiatric disorders, inability to understand Swedish, allergy to chlorine, or plans to start other treatments during the study period. The patient examination was carried out by a trained physical therapist under the supervision of a rheumatologist. The patients completed a pain location sheet and were interviewed using a standardized questionnaire. They were asked about their present symptoms using a dichotomized yes or no scale. If the patient was unclear about having the symptom at the present time, "no" was registered. Those working outside the home were asked about their experience of physical or psychological strain at work. The tender points were examined using the protocol described by Wolfe, *et al*^K

Patients were randomized to either a training group (37 patients) or a control group (32 patients) using sequential allocation according to age and symptom duration²⁰. The patients were all instructed to continue their baseline medical treatment with no change throughout the 6 month period. Eleven patients dropped out, 9 in the training group and 2 controls. Seven patients in the training group dropped out before they started their pool training or within the first few sessions and 2 more dropped out after 6 sessions. The main reasons for not starting or interrupting the program were lack of time due to commitments relating to child care or employment, or the occurrence of infection or injury. Two patients in the control group declined to come to the second examination. As a result, 28 patients belonging to the training group and 30 belonging to the control group completed the study. At study entry, 57 patients (98%) reported fatigue, 50 (86%) morning stiffness, 45 (78%) recurrent headache, 45 (78%) sensitivity to weather changes, 40 (69%) poor sleep, 33 (57%) feeling depressed, 33 (57%) anxiety, and 30 (52%) irritable bowel symptoms. Demographic data for the sample that completed the study (n = 58) and patients who dropped out of the treatment group (n = 9) are provided in Table 1. No significant differences were found between patients in the treatment group (n = 28) and the control group (n = 30) in terms of the symptoms, primary outcome variables, or demographic variables other than the number of patients taking nonsteroidal antiinflammatory drugs (NSAID), which was significantly higher in the control group compared with the treatment group (p = 0.046) (Table 1). No significant differences were found between patients in the training group and patients who dropped out of the training group in any of these variables (Table 1).

Description of the program. The patients performed an exercise program in a temperate pool, supervised by a physical therapist (PT), once a week for 6 months in groups of 6-10 patients. The study started with the first groups at the end of 1997. The pool was closed for 2 months in the summer and 3 weeks at Christmas, and the training period was increased by the number of sessions that were missed during the break. Each session lasted 35 min and comprised exercises for endurance, flexibility, coordination, and relaxation. The patients were instructed to exercise in their own rhythm and to modify the exercises individually with respect to threshold of pain and fatigue. The mean attendance rate at the sessions was 70%. Details of the program are provided in Appendix 1.

The education program consisted of six 1 h sessions led by one of the PT who supervised the pool training, and was based on the active participation of the patients. The aim of the program was to introduce strategies to cope with the FM symptoms and to encourage physical activity^{14,21,22}. The main topics of the discussions were symptoms, explanatory theories for long lasting pain,

modes of physical training and relaxation, and modifications of the patient's lifestyle. The course literature was a brochure for patients with FM²³ and a book for patients with pain²⁴. Details of the program are provided in Appendix 2.

Outcome measures. The total score of the disorder-specific instrument, the Fibromyalgia Impact Questionnaire (FIQ)²⁵, and the 6 min walk test²⁶ were chosen as the primary outcome measures. The subscales of the FIQ were regarded as the secondary outcome measurements. A number of functional tests measuring limitations in upper and lower extremities in FM were included as well as generic instruments assessing severity of symptoms, psychological distress, disabilities, self-efficacy, and quality of life. The treatment did not include any components addressing interpersonal or working conditions, and thus the subscales of the outcome instruments measuring these issues were not expected to show any significant changes after treatment.

Questionnaires. The following self-administered questionnaires were completed by the patients both before the study start and after 6 months. *The Fibromyalgia Impact Questionnaire.* The FIQ, a brief 10 item instrument, was developed and validated for a FM population²⁵. The patients who did not work were allowed to leave the FIQ job ability subscale blank. The instrument has been validated for a Swedish FM population and the Swedish version of the instrument was used in the study²⁷.

The Short-Form 36. The SF-36 is a generic health status instrument that is widely used and has been validated for Swedish populations²⁸. *The Swedish version of the Multidimensional Pain Inventory (MPI-S).* The MPI-S is a generic psychometric inventory measuring the perception of pain and its consequences, and consists of 3 sections, of which sections 1 and 2 were applied in the study. The reliability and factor structure of the modified Swedish version have been found to be satisfactory for patients with long lasting pain²⁹.

The Arthritis Self-Efficacy Scales (ASES-S). The ASES-S is a 20 item instrument divided into 3 subscales³⁰. The ASES-S has been validated for Swedish patients with RA and long lasting pain³¹.

The Arthritis Impact Measurement Scales (AIMS). The AIMS subscales measuring anxiety and depression were applied³². The AIMS are validated for Swedish arthritis populations³³.

The Quality of Life Questionnaire (QOLS). The QOLS is a generic instrument validated for patients with rheumatic diseases in Sweden³⁴.

Experience of the program and changes in lifestyle and physical activity level and use of relaxation techniques during the program period were explored by means of a questionnaire that patients in the training group filled out after the end of the program.

Tests of functional limitations. A trained PT, who remained blinded to the training randomization, assessed the functional limitations of the patients before the study start and after 6 months. The reliability of the measurements has been evaluated for FM populations^{7,35}, and the tests are described in the order they were performed, as follows.

The 6 min walk test was recorded in meters²⁶. The patient's heart rate and ratings of perceived exertion³⁶ were recorded before and after the test. The walk test was not completed by a visually handicapped woman.

The chair test assesses endurance of the lower extremities²⁶.

Shoulder range of motion: Forward and lateral elevation were recorded from 0 to 4, where 0 = 180-151, 1 = 150-131, 2 = 130-91, 3 = 90-61, 4 = 60-0 degrees. Hand to scapula and hand to neck motions were scored on a 0-4 scale, and the scores 0 and 1 were transformed to 0 in the hand to neck assessment²⁶. The mean value of the 4 assessments was used in the statistical calculations.

Grip strength was measured as the maximum and mean strength⁷.

Shoulder abductor endurance was measured in 90° abduction²⁶.

A pretest questionnaire of a patient belonging to the control group was found to be missing, and thus the analyses of the questionnaires in the control group comprised 29 patients. The AIMS was sent to the patients 2 weeks after the program started and was not received by 2 patients in the training group. Four patients in the training group did not answer the FIQ subscale of feeling

Table 1. Demographic data at study entry.

	Control Group, n = 30 Mean (%)	Treatment Group, n = 28 Mean (%)	Treatment Group, dropouts, n = 9 Mean (%)
Age, yrs	47 (SD 11.6)	45 (SD 8.0)	42 (SD 9.3)
Symptom duration, yrs	8.9 (SD 7.2)	8.4 (SD 6.0)	7.3 (SD 5.2)
Tender points, n	15.7 (SD 2.0)	16.3 (SD 1.8)	15.1 (SD2.1)
Education level, yrs	11.7 (SD 3.9)	11.5(SD2.9)	11.6(SD2.7)
FIQ, total score 0-10	7.0(1.9)	6.6(1.7)	6.8(1.8)
6 min walk test, m	492 (79)	467(100)	493 (82)
Employment status.	8(27)/9(30)/13(43)	7(25)/9(32)/12(43)	2 (22)/0 (0)/7 (7)
full time/part time/none			
Perceived work load ¹⁻²			
Physical	5(29)	6(38)	1 (50)
Psychological	12(70)	12(75)	1(50)
Sick leave			
Full time	6(20)	3(11)	3(33)
Part time	5(17)	6(21)	0(0)
Disability pension			
Full time	4(13)	5(18)	3(33)
Part time	5(17)	3(11)	0(0)
Social status			
Married, cohabiting	17 (57)	23 (82)	7(78)
Not living with another adult	13 (43)	5(18)	2(22)
Children living at home, yes	15 (50)	14 (50)	6(67)
Drugs ³			
Simple analgesics	14 (47)	9(32)	4(44)
NSAID	12(40)	4 (14)*	0(0)
Psychotropics ⁴	11 (37)	11(39)	3(33)

*The number of patients using NSAID was significantly lower in the training group compared with the control group ($p = 0.046$). No other significant differences were found between the treatment group and the control group, or between the treatment and the dropout group ($p = 0.05$).

¹Only those working outside the home are included; training group $n = 16$, control group $n = 17$.

²The patients could answer yes to both questions.

³The patients could use more than one medicine.

⁴Antidepressants, sedatives.

bad, and 3 patients belonging to the control group did not fully complete the QOLS. Two further values were found to be missing in the questionnaires of subjects of the training and control group. The means of the pre- and post-test ratings are given for all the patients who completed the questionnaires (Tables 2 and 4), and differences are counted for the subjects who answered the questions on both occasions.

Statistical methods. Fisher's nonparametric permutation test was used for comparison of changes between the 2 groups, and Fisher's nonparametric permutation test for matched pairs was used to analyze changes within groups over time³⁷. Fisher's exact test was used to compare proportions between the groups. Adjustment for differences in baseline variables was based on Mantel's technique of pooling³⁸ applied to Fisher's permutation test. The significance level was set at 0.05.

RESULTS

Baseline data. Means and standard deviations (SD) of measurements at the pretest assessment are shown in Tables 2, 3, and 4. There were no significant baseline differences between the 2 groups in the performances of the functional tests. However, 6 of a total of 33 variables of the self-administered

instruments showed significant between-group differences at baseline. Patients in the training group assessed their general health on the SF-36 ($p = 0.03$), mental health on the SF-36 ($p = 0.03$), social support on the MPI ($p = 0.04$), self-efficacy for pain ($p = 0.02$) and the symptoms ($p = 0.04$) on the ASES as higher, and the degree of depression on the FTQ ($p = 0.02$) as lower than patients in the control group. Adjustment for the differences in baseline variables did not change the results of the between-group analyses.

Between-group differences. Means and SD of the differences between the post-test and pre-test values are shown in Tables 2, 3, and 4. Significant improvements were found for the 2 primary outcome variables, the FIQ total score ($p = 0.017$) (Table 2) and the distance covered during the 6 min walk test ($p < 0.0001$) (Table 3), in the training group compared with the control group. Regarding the secondary outcome variables, the FIQ physical functioning ($p = 0.001$) and anxiety ($p = 0.019$) were found to be improved in the training group

Table 2. The ratings at the pre-test and after 6 months in the training and control groups on the Fibromyalgia Impact Questionnaire (FIQ). Means and SD for the ratings and the differences of the changes within the groups, as well as significant differences of the differences within and between the groups, are given.

	Training Group, n = 28			Control Group, n = 29			Differences Between Groups
	Pretest Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	Pre-test Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	P
FIQ							
Total score	6.6(1.7)	5.7(1.9)	-0.9(1.3)**	7.0(1.9)	7.0(1.9)	0.0(1.4)	0.017
Physical function	5.7(2.2)	4.8(2.2)	-0.9(1.6)**	5.1(2.0)	5.5(2.1)	0.4(1.3)	0.001
Feel bad	7.9(2.7)	6.8(2.8)	-1.3(3.2)	8.2(2.5)	8.1(2.2)	-0.1(2.5)	NS
Work missed	4.8(4.2)	4.6(4.1)	-0.2(2.5)	6.5(4.5)	6.4(4.3)	-0.1(3.3)	NS
Job ability	7.0(2.3)	6.6(2.3)	-0.3(1.5)	6.7(2.8)	6.8(2.7)	0.1(3.4)	NS
Pain	7.8(1.9)	6.6(2.2)	-1.2(2.3)*	7.3(2.2)	7.1(2.6)	-0.2(2.1)	NS
Fatigue	8.2(1.7)	7.3(2.1)	-0.9(1.6)**	7.9(2.4)	7.8(2.4)	-0.1(1.9)	NS
Morning tiredness	7.9(2.4)	7.3(2.4)	-0.6(1.6)	8.1(2.2)	8.2(1.7)	0.2(2.0)	NS
Stiffness	7.3(2.5)	5.9(3.0)	-1.4(2.3)**	7.4(2.4)	7.2(2.2)	-0.2(2.6)	NS
Anxiety	5.1(3.0)	3.9(3.0)	-1.3(3.1)*	6.2(2.9)	6.8(3.0)	0.5(2.6)	0.019
Depression	4.4(3.2)	3.6(3.2)	-0.8(3.4)	6.5(3.1)	6.2(3.1)	-0.3(2.3)	NS

*p<0.05, **p<0.01.

Table 3. Functional tests at the pre-test and after 6 months in the training and control groups. Mean and SD for the assessments and the differences of changes within the groups, as well as significant differences of the differences within and between the groups, are given.

	Training Group, n = 28			Control Group, n = 30			Difference Between Groups
	Pre-test Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	Pre-test Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	P
6 min walk test	467(100)	506(99)	39.6(44.7)**	492(79)	477(81)	-15.2(44.5)	<0.0001
Chair test	15(7)	17(8)	1.6(4.0)*	15(6)	14(7)	0.5(3.2)	NS
Grip strength, 10 s							
Right	138(67)	155(78)	17.9(48.2)	134(67)	130(76)	-4.4(48.2)	NS
Left	128(61)	153(76)	27.4(41.4)**	129(70)	130(75)	0.9(38.3)	0.013
Grip strength, max							
Right	170(77)	190(86)	20.0(54.4)	162(78)	158(91)	-3.0(61.9)	NS
Left	156(73)	185(93)	33.7(49.3)**	161(87)	161(93)	-0.3(40.7)	0.005
Shoulder motion							
Right	0.6(0.6)	0.6(0.6)	0.0(0.5)	0.6(0.6)	0.7(0.7)	0.1(0.6)	NS
Left	0.5(0.5)	0.5(0.6)	0.0(0.7)	0.5(0.6)	0.6(0.5)	0.0(0.4)	NS
Shoulder endurance							
Right	50(47)	40(25)	-10.0(25.4)*	61(41)	44(29)	-17.1(31.5)**	NS
Left	52(43)	51(40)	-1.8(32.1)	55(40)	40(26)	-14.4(29.7)**	NS

*p<0.05, **p<0.001.

compared with the control group (Table 2). The maximum grip strength of the left hand (p = 0.005) and grip strength during 10 s (p = 0.013) showed significant improvements in the training group compared with the control group (Table 3). The SF-36 general health (p = 0.022) and social functioning (p = 0.049); the MPI-S pain severity (p = 0.045) and affective distress (p = 0.036); the AIMS depression (p = 0.045) and anxiety (p = 0.015); and the QOLS (p = 0.011) were found to have improved in the training group compared with the control group (Table 4).

Within-group differences in the training group. Significant within-group changes are marked with asterisks in Tables 2, 3,

and 4. The following scores of the FIQ were found to be improved: the FIQ total score (p = 0.003), physical functioning (p = 0.004), pain (p = 0.01), fatigue (p = 0.004), stiffness (p = 0.002), and anxiety (p = 0.03) (Table 2). The 6 min walk test (p = 0.0001), the chair test (p = 0.04), and both maximum grip strength (p = 0.006) and the 10 s grip strength of the left hand (p = 0.0007) were found to be increased, while shoulder endurance for the right arm was decreased (p = 0.048) (Table 3). The following scores were found to be improved in the SF-36: physical functioning (p = 0.003), bodily pain (p = 0.03), general health (p = 0.01), vitality (p = 0.001), and social functioning (p = 0.04). Scoring of pain severity was found to be

Table 4. The ratings at the pretest and after 6 months in the training and control groups on the generic instruments. Means and SD for the ratings and the differences of the changes within the groups, as well as significant differences of the differences within and between the groups, are given.

	Training Group, n = 28			Control Group, n = 29			Differences Between
	Pre-test Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	Pre-test Mean (SD)	6 months Mean (SD)	Difference Mean (SD)	Groups P
SF-36							
Physical functioning	44.3 (20.0)	51.9(19.5)	7.5(12.0)**	47.5(16.0)	47.3(18.3)	-0.2(17.0)	NS
Role physical	16.1 (29.0)	25.0 (32.6)	8.9(31.3)	14.9(28.1)	10.8(29.1)	-3.7(21.2)	NS
Bodily pain	24.7(17.4)	32.9 (20.2)	8.2(19.0)*	21.9(14.7)	24.0(19.1)	2.2(14.2)	NS
General health	38.3(16.8)	45.6(19.0)	8.4(16.6)*	27.9(18.8)	26.3(16.3)	-1.6(15.0)	0.022
Vitality	22.5 (14.5)	35.3(21.9)	12.8(18.6)**	21.8(22.4)	24.8 (18.4)	3.0 (20.7)	NS
Social functioning	46.9 (26.9)	56.7 (29.2)	9.8(24.1)*	45.7 (27.6)	43.1 (25.6)	-2.6 (22.3)	0.049
Role emotional	47.6 (43.9)	54.8 (46.4)	7.1 (57.6)	28.9 (40.2)	26.4(41.2)	-3.5 (28.7)	NS
Mental health	59.9 (20.4)	63.2(22.1)	3.3(18.6)	46.2 (26.5)	49.7(21.9)	3.5(18.9)	NS
MPI-S							
Pain severity	4.2 (0.9)	3.8(1.0)	-0.4(1.1)*	4.2(1.2)	4.3(1.3)	0.1 (1.0)	0.045
Interference	4.1 (1.2)	3.9(1.2)	-0.2 (0.7)	4.3(1.3)	4.3(1.3)	0.0 (0.8)	NS
Life control	2.8(1.2)	3.2(1.2)	0.4(1.2)	2.4(1.3)	2.2(1.2)	-0.2(1.1)	NS
Affective distress	3.1 (1.4)	2.8(1.6)	-0.4(1.3)	3.6(1.7)	4.0(1.7)	0.3(1.1)	0.036
Social support	4.2(1.7)	4.1 (1.7)	-0.1 (1.3)	3.3(1.6)	3.3(1.8)	0.1 (1.4)	NS
Punishing	1.5 (1.6)	1.8(1.5)	0.3(1.1)	1.7 (2.0)	1.6(1.9)	-0.1 (1.2)	NS
Sollicitous	3.2(1.5)	3.0(1.5)	-0.2 (0.6)	2.5 (1.4)	2.4(1.6)	-0.2(1.2)	NS
Distracting	3.5(1.4)	3.7 (1.4)	0.2(1.5)	2.8(1.2)	3.1 (1.7)	0.1 (1.6)	NS
ASES							
Pain	44.2 (20.4)	45.6 (20.7)	1.7(11.2)	32.0 (17.2)	35.5 (18.7)	3.5(11.5)	NS
Function	60.6 (25.0)	64.5 (24.8)	3.9 (19.5)	62.7 (21.6)	63.4 (22.8)	0.7 (17.3)	NS
Symptom	50.2 (20.2)	54.2 (20.2)	4.0 (15.7)	39.9 (19.6)	40.2 (20.3)	0.4 (14.2)	NS
QOLS							
	4.7 (0.9)	4.8 (0.9)	0.2 (0.6)	4.4(1.0)	4.2 (1.0)	-0.3 (0.7)*	0.011
AIMS							
Depression	3.5 (2.0)	3.2 (2.0)	-0.3 (1.4)	4.4 (2.6)	4.9 (2.4)	0.6 (1.8)	0.044
Anxiety	5.3 (2.1)	5.1 (2.0)	-0.3 (1.7)	5.9 (2.6)	6.6 (2.5)	0.7 (1.3)*	0.015

*p < 0.05, **p < 0.01.

improved in the MPI-S ($p = 0.04$) (Table 4). The mean number of tender points did not change significantly between the test occasions, being 15 (SD 3.3) at the post-test assessment.

Within-group differences in the control group. At the 6 month examination, shoulder endurance for both the right arm ($p = 0.005$) and the left arm ($p = 0.008$) was found to be decreased (Table 3), the QOLS had decreased ($p = 0.049$), and anxiety had increased, according to the AIMS subscale ($p = 0.01$) (Table 4). The mean number of tender points was unchanged; it was 16 (SD 2.4) at the post-test assessment.

Patients' experience of the program. The 2 main themes identified in the patients' descriptions of their experiences of the program were the importance of sharing experiences of symptoms and difficulties with other patients and the sense of pleasure during exercising in the pool. The former theme included the feeling of being understood, receiving confirmation, getting hope, and gaining insight into the fact that it was possible to do something about the symptoms and future well being. The sense of pleasure during exercising in the pool included joy about a mode of physical training that did not increase pain, a newly discovered ability to relax in the water, diminished stiffness, and increased fitness. A few patients

wished to extend the number of patient education sessions and 2 patients wished to exercise twice a week. *Changes in lifestyle.* Twenty-two patients in the training group (79%) reported that they had made some changes to their lifestyle. The main theme was enhancement of their own well being by making priorities in their everyday life based on their own needs and resources, accepting their own limits, starting to say no to others, and increasing their level of physical activity. Fourteen patients (50%) had increased their level of physical training.

A total of 22 patients in the training group (79%) reported that they did some kind of physical training besides pool training, mainly low intensity walks outdoors. Fifteen patients (54%) performed some kind of regular physical activity (mainly low intensity walks) for 30 min at least 2-3 times a week. Nineteen patients (68%) did some kind of regular relaxation exercises.

DISCUSSION

The primary outcome measures, the FIQ total score and the 6 minute walk test, showed significant improvements in the training group compared with the control group, confirming

that the 6 month program of pool exercise and education had positive effects with regard to the consequences of FM. Of the secondary outcome measures, the subscales of the FIQ, physical function (disability) and anxiety, showed significant improvements when the treatment group was compared with the control group. The between-group improvements were supported by several within-group improvements in the ratings of the treatment group, while no within-group improvements were found for the control group. These results are in agreement with the results of a previous 6 month study of education and physical exercise for patients with FM³⁹.

Grip strength in the left hand was found to have increased significantly in the training group compared with the control group and a similar tendency was also apparent in the right hand. These findings support reports of increased hand grip strength after physical exercise in patients with FM¹². However, a deterioration in shoulder function was found in both the treatment group and the control group at the end of the 6 month period. The improvement in walking ability was supported by within-group improvements in the walk and chair tests in the training group, while no improvements were seen in the control group. The improvement in walking ability is in line with results from previous studies¹⁹⁻³⁹. It is reasonable to suppose that the endurance, coordination, and stretching exercises in the pool resulted in improved walking ability. However, half the patients in the training group reported that they had increased their level of physical activity during leisure time, mainly low intensity walks outdoors. A similar increase in the reported frequency of walks outdoors was noted in a study evaluating the effects of education in FM¹⁴, but did not result in any improvements in the 6 min walk test¹⁴. Accordingly, we do not expect these changes in lifestyle to improve walking ability, but a supervised exercise program appears to be needed to achieve these results.

Pain and other symptoms associated with FM affect the patient's life on many levels. Several self-administered instruments were applied to the patients' perceptions of health. Analyses of the ratings in the generic instruments, the SF-36, MPI-S, QOLS, and the arthritis-specific AIMS, showed that patients in the training group assessed their ill health and distress as being less severe after the treatment period compared with the ratings of the control group (Table 4). Since these changes were found in more than one instrument, they lend support to the hypothesis that these dimensions might have been improved as a result of the treatment program, which is in line with the results of previous studies evaluating the effects of education and physical treatment in FM^{19-39,40}.

No changes were found for section 2 of the MPI-S, which was not anticipated either, since the program did not address questions concerning patients' relationships to their partners, as in another study in which the same instrument was used⁴¹. The ASES, measuring self-efficacy, revealed no significant improvements, which seems surprising since both the quantitative and qualitative data indicated improvements that may

be associated with increased self-efficacy. There are several possible explanations, one being a wide SD of the mean scores and the mean changes. Different patterns or subgroups in the FM population have been identified^{40-42,43}, and it has been suggested that the outcomes should be analyzed separately for the patients in different subgroups, since they may respond differently to the treatments offered⁴⁰. However, our study population was too small for subgroup analyses.

When several instruments are applied, there is always a risk of false significances due to multiple comparisons. In this study, the FIQ total score and the 6 min walk test were designated the primary outcome measures. The differences between the groups were highly significant for both these variables. When it came to analysis of the 10 secondary variables (the subscales of the FIQ), the FIQ physical function would have remained significant if the Bonferroni correction had been applied, while the FIQ anxiety would not. No *a priori* hypotheses were made for the other tests and instruments applied in the study. The reason for including them was largely exploratory and therefore no correction for multiple comparisons was made for them.

The main themes in the patients' experiences of the program were the importance of sharing experiences of symptoms and difficulties with other patients and the sense of pleasure during exercising. Seventy-nine percent of the participants reported that they had made positive changes to their lifestyle, compared with 71% and 80% in previous studies¹⁴⁻⁴⁴. The changes of lifestyle described by the patients in the present study were found to be related to enhancement of their own well being, corresponding to the earlier studies that described the changes as new ways of coping with symptoms¹⁴ and adjustments of daily life⁴⁴. Qualitative explorative studies are needed to obtain a deeper understanding of the meaning that the changes in lifestyle have for patients with FM, knowledge that would be valuable when developing treatment programs for this patient group.

The mean age of the patients was 46 years, which is comparable to previous intervention studies of FM^{14-19,39-41}, but higher than that in one study¹². The mean FM symptom duration is comparable to that found in earlier studies⁶¹⁴. In addition to pain, a high frequency of other symptoms was reported by the patients. More than 75% of the patients reported fatigue, morning stiffness, recurrent headache, and sensitivity to weather changes, and almost 70% reported poor sleep. More than 50% reported feeling depressed, being anxious, and having irritable bowel symptoms. It may, however, be difficult to assess the value of these results due to the methodology that was used. If the patient was unsure about whether at the present time she did or did not have a symptom that was asked for, the answer was regarded as negative. The patients' ratings of the severity of their symptoms on the questionnaires may reflect the severity of FM symptoms in this patient population more effectively than the dichotomized "yes or no" data.

The study population is small, which may limit the conclusions. Although an effort was made to motivate the patients to continue the study, 24% of patients from the treatment group and 6% from the control group dropped out. The characteristics of patients who dropped out of the treatment group are presented in Table 1, and they did not differ significantly from those who completed the treatment program. However, it would have been interesting to analyze how motivated the patients were. Lack of time and concomitant diseases were the main reasons for interrupting or not beginning the program. High dropout rates, up to 40%^{10,2}, have been reported in studies of physical training in patients with FM, and a study of women with musculoskeletal disorders revealed that the patients had difficulty finding time for treatment due to their family duties⁴⁵. The dropouts were not included in the post-treatment analyses.

We cannot exclude the possibility that the interaction between the physical therapists and the patients during the treatment period might have influenced some of the outcomes. Movement therapy that is adapted to the resources of the patients and the interaction skills of physical therapists is expected to enhance the health of patients with psychosomatic symptoms^{46,47}. As interaction is an essential part of physical therapy treatment, it is difficult to conceive of an "attention-placebo physical therapy" that would not have a beneficial effect in one way or another on the placebo group. Unlike drug studies, which are easily blinded, behavioral and physical treatment requiring the active participation of patients is virtually impossible to blind or make inert.

In this study design, we compared the treatment group with the control group, which continued their usual activities with no contact with physical therapists at the department where the study was conducted. For ethical reasons we could not ask the patients in either group to interrupt the activities they were already engaged in, but we asked them not to start any new treatment during the study period. At the end of the 6 month period, 4 patients in each group said that they had received massage or ultrasound, but that these modes of treatment had been of short duration. Since the conditions were similar in both groups, we have no reason to believe that the results were biased by these factors.

Physical exercise performed in a temperate pool was found to be a suitable treatment modality in FM, providing opportunities for the individual adjustment of exercise to perceived pain and fatigue. Whenever appropriate, individual help was given to modify the load and performance of exercises. The same movements were repeated several times in order to give the patients, many of whom had reported stress in their daily life at study entry, an opportunity to find their own rhythm and harmony while exercising. The initial planned training intensity was somewhat high, but it was lowered as many patients reported increased pain for 3-4 days after the training sessions. This in turn may have been a disadvantage for those patients who would have preferred to train harder. As only a

few patients were willing to come for sessions twice a week, the pool training was only performed once a week. The treatment program was not designed to increase aerobic capacity, but to improve well being and overall function in patients. The patient education component was based on the patients' active participation, comprising a total of 6 hours. Afterwards many patients expressed a wish to increase this part of the program. To implement the program in clinical practice, it is suggested that the education program should be extended and shared by members of a multidisciplinary team. However, further studies are needed to optimize the effects of such programs.

The results indicate that 6 months of exercise in a temperate pool combined with education improve the consequences of fibromyalgia syndrome, confirming the positive results of previous studies.

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Appendix 1. Description of the exercises in a temperate pool. Each session lasted for 35 min. The aims of the program were to enable the patient (a) to perform the movements, described below (1-7), with awareness and to find her own rhythm and harmony when exercising, to learn the limits and possibilities of her body; (b) to enable her to apply this new knowledge in other physical activities; (c) to increase her motivation for physical activity; and (d) to improve function. At the start and when new patients entered the group, the leader demonstrated all the movements at a slow and smooth pace, emphasizing that everyone should adjust the exercises individually with respect to their threshold of pain and fatigue. When the participants had learnt the exercises, and performed them correctly, the pace was increased for those who accepted it. Individual instructions were given whenever needed.

1. Walking forward and backward, or jogging forward, in the water. Either paddling with the arms in order to achieve resistance, or smoothly stroking the arms in the water.
2. Arm movements and knee bending when standing. The patients were instructed to select the pace and resistance (by positioning of the hands during the movement) with respect to their current threshold of pain.
3. Jogging or walking on the spot combined with arm movements.
4. Relaxation and breathing exercises.
5. Jogging on the spot, alternatively jumping with one leg forward and the other backward. The exercise was alternated with bicycling in a supine position.
6. Stretching of the hamstrings, the quadriceps and iliopsoas muscles, outward rotators and abductors of the hip, the gastrocnemius muscle, the trapezius muscle, and the levator scapulae muscle. Individual instruction of stretching of other painful or shortened muscles when appropriate.
7. Relaxation, performed either standing and leaning against the wall or lying supine. Air-filled tires and neck-collars were provided.

Appendix 2. The education program.

The education program consisted of six 1 h sessions, once a week, and was based on the active participation of the patients. The aim was to introduce strategies to cope with the FM symptoms and to encourage physical activity. The study literature comprised a brochure for patients with FM and a book for patients with long lasting pain, with no focus on any diagnoses.

The topics of the education program were:

1. Symptoms, and explanatory theories for long lasting pain. The session started with listing of the patients' symptoms on a flip chart, followed by a discussion of their experiences. A short presentation of the theories on periph-

eral, centra], psychological and sociological theories for long lasting pain was given, followed by discussion of the patients' own theories and beliefs.

2. Pain and pain alleviation. A short presentation of the local (gate theory) and central (CNS) levels of pain modulation was given, followed by discussion of the patients' experiences of pain alleviation. An attempt was made to motivate the patients to use different techniques of pain alleviation, including physical activity and relaxation. A short relaxation exercise was done while seated.

3. Stress, pain, and depression. Physical training. Listing of the patients' experiences of stress symptoms on the flip chart, followed by discussion of the patients' experiences on how to alleviate stress. Presentation of a low impact mode of exercising in FM. A short relaxation exercise when seated.

4. Relaxation and body awareness. Short presentation of a theory of active (physical training, music, reading) and passive (different modes of relaxation) modes of relaxation. A short relaxation exercise when seated.

5. Lifestyle. Identification of possible causes that may increase pain and discussion of possibilities of doing something about them. The participants were asked to write down their own plans for changes, according to an example given in the study literature.

6. Discussion of the same topic as at session 5.

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