

# Biofeedback/Relaxation Training and Exercise Interventions for Fibromyalgia: A Prospective Trial

Susan P. Buckelew, Robert Conway, Jerry Parker, William E. Deuser, Joan Read, Thomas E. Witty, John E. Hewett, Marian Minor, Jane C. Johnson, Lynn Van Male, Matthew J. McIntosh, Margaret Nigh, and Donald R. Kay

**Objective.** To compare the effectiveness of biofeedback/relaxation, exercise, and a combined program for the treatment of fibromyalgia.

**Methods.** Subjects ( $n = 119$ ) were randomly assigned to one of 4 groups: 1) biofeedback/relaxation training, 2) exercise training, 3) a combination treatment, or 4) an educational/attention control program.

**Results.** All 3 treatment groups produced improvements in self-efficacy for function relative to the control condition. In addition, all treatment groups were significantly different from the control group on tender point index scores, reflecting a modest deterioration by the attention control group rather than improvements by the treatment groups. The exercise and combination groups also resulted in modest improvements on a physical activity mea-

sure. The combination group best maintained benefits across the 2-year period.

**Conclusion.** This study demonstrates that these 3 treatment interventions result in improved self-efficacy for physical function which was best maintained by the combination group.

**Key words.** Fibromyalgia; Exercise; Biofeedback.

## INTRODUCTION

Fibromyalgia syndrome (FMS), a nonarticular rheumatic disorder, affects approximately 6 million Americans (1). FMS is characterized by diffuse pain, disturbed sleep, tender points (2,3), and impaired functional ability (4,5). Despite the prevalence of the disorder and the severity of the symptoms, the pathophysiology is not well understood. Interventions such as exercise and cognitive-behavioral treatment programs are often included in the comprehensive rehabilitation care of people with FMS; however, well-controlled trials examining these interventions are limited.

Three prospective controlled trials of the effectiveness of exercise for FMS have been reported (6-8). A 12-week aerobic conditioning exercise program resulted in improvements on myalgic scores and patient and physician global ratings, relative to a group flexibility training program (6). No significant group changes were found on self-report pain, percentage of body affected, or sleep measures (6). A second controlled exercise trial examined the effectiveness

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Susan P. Buckelew, PhD, Robert Conway, MD, Jerry Parker, PhD, William E. Deuser, PhD, Joan Read, MEd, Thomas E. Witty, PhD, John E. Hewett, PhD, Marian Minor, PhD, Jane C. Johnson, MA, Lynn Van Male, MA, Matthew J. McIntosh, MS, Margaret Nigh, BGS, and Donald R. Kay, MD, Department of Physical Medicine and Rehabilitation, Missouri Arthritis Rehabilitation Research and Training Center, School of Medicine, University of Missouri-Columbia.

Address correspondence to Susan P. Buckelew, PhD, 1411 Sullabella Drive, Columbia, MO 65203.

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of biweekly 60-minute low-impact aerobic dance sessions. Relative to a non-treatment control group, an exercise group demonstrated significant improvements on upper extremity dynamic endurance measures only. There were no significant changes on pain, pain coping, or fatigue measures. The 39% dropout rate in the exercise portion of the study limits the generalizability of the study results (7). Similarly, Martin et al (8) found that a 6-week flexibility, strengthening, and walking program resulted in improved tender point scores and aerobic fitness measures relative to a relaxation control group. There was a 40% dropout rate among subjects in the exercise condition. Nevertheless, these studies suggest that aerobic exercise intervention can help manage some symptoms of FMS.

A controlled biofeedback trial (9) with 12 subjects found pre-intervention to post-intervention improvements on tender points, a clinical questionnaire, self-report pain measures, and morning stiffness for subjects participating in the biofeedback condition. No significant improvements were reported in a false-biofeedback group. Between-group differences were not reported, likely due to the small sample size. Goldenberg et al (10) studied the effectiveness of a 10-week outpatient group meditation-based cognitive-behavioral treatment program utilizing nonrandomized control groups. Significant improvement in self-report pain and psychologic distress relative to the control group was reported.

Several studies have reported outcomes of programs integrating a psychologic and an exercise component. Burckhardt et al (11) examined the effectiveness of a self-management education program alone or with a physical training program relative to a no-treatment control group. Both the experimental groups improved on self-efficacy measures and quality of life measures relative to the no-treatment control group.

Wigers et al (12) reported short- and long-term effects of an aerobic exercise, stress management, or a "treatment as usual" control group. The aerobic exercise condition resulted in improvements in pain distribution, dolorimetry, and work capacity scores, which were not maintained at followup. Stress management resulted in improvements on dolorimetry scores, which were maintained at 4-year followup.

Utilizing a quasi-experimental design, Nielson et al (13) examined a 3-week comprehensive inpatient pain management treatment including medication management, relaxation training, cognitive techniques, aerobic exercises and stretching, pacing, family education, and in vivo rehearsal. Statistically significant improvements were found at posttreat-

ment in pain severity, emotional distress, and pain behavior measures. Statistically significant improvements in emotional distress and pain behavior measures were maintained at 30-month followup (14).

Bennett et al (15) reported significant improvements on Fibromyalgia Impact Questionnaire scores and Tender Point Index scores following a 6-month outpatient comprehensive pain management treatment program. Mengshoel et al (16) also reported significant improvements in pain following the completion of a 10-week multidisciplinary outpatient program. Neither study utilized an attention control group.

Although studies of treatment outcome suggest that exercise and biofeedback may result in modest improvements in FMS, the relative efficacy of the treatments alone and in combination has not been studied. This study was designed to assess treatment efficacy (biofeedback/relaxation training, exercise, and the combination) on a comprehensive range of outcome measures immediately after a 6-week intervention, and at 3-month, 1-year, and 2-year followup. The expectation was that each of the 3 active treatment groups would show improvements relative to the attention control group.

## PATIENTS AND METHODS

**Subjects and sample description.** Subjects were referred by their personal physicians, including rheumatologists and psychiatrists, at a large midwestern university hospital and a rheumatology private practice. To qualify, subjects were required to meet Yunus' criteria for the diagnosis of FMS (2,3,17). The American College of Rheumatology (ACR) criteria (18) were not available at the beginning of the project. Yunus' criteria require: 1) a minimum of 5 of 20 possible tender points, 2) generalized aches and pains or prominent stiffness involving at least 3 anatomic sites, and 3) the presence of at least 3 out of 10 possible minor criteria. Yunus' minor criteria include the following: 1) modulation of symptoms by physical activity, 2) modulation of symptoms by weather factors, 3) modulation of symptoms by anxiety or stress, 4) poor sleep, 5) general fatigue, 6) anxiety, 7) chronic headaches, 8) irritable bowel syndrome, 9) subjective swelling, and 10) numbness.

Subjects were excluded from the study if any of the following conditions were present: 1) organic brain syndrome, 2) psychotic disorder, 3) unstable or uncontrolled medical condition, 4) major communicative disorder, 5) rheumatoid arthritis, 6) widespread osteoarthritis, 7) subjective pain of less than 4

Table 1. Pretreatment demographic and clinical characteristics

	Biofeedback (n = 29)				Exercise (n = 30)				Combination (n = 30)				Attention Control (n = 30)			
	%	Mean	SD	Median	%	Mean	SD	Median	%	Mean	SD	Median	%	Mean	SD	Median
Age, years	-	44.1	9.6	45.0	-	45.6	9.4	46.0	-	41.9	8.1	41.5	-	44.3	11.2	46.0
Duration of fibromyalgia symptoms, years	-	11.6	10.0	9.5	-	11.6	8.9	9.3	-	12.9	9.3	10.7	-	10.0	9.0	9.0
Duration of fibromyalgia diagnosis, years	-	2.5	2.9	0.9	-	3.0	3.4	1.6	-	2.8	3.0	1.6	-	2.5	2.4	1.6
Education level, years	-	13.0	2.5	13.0	-	13.8	2.5	13.0	-	13.4	2.7	12.5	-	13.0	2.2	12.0
Number of tender points	-	15.9	3.7	17.0	-	15.8	4.3	17.0	-	14.0	4.9	14.0	-	14.9	4.2	16.0
Socioeconomic status	-	39.9	15.6	40.0	-	33.8	14.3	29.5	-	42.6	17.5	40.0	-	38.6	14.7	37.0
Sex, % female	96.6	-	-	-	93.3	-	-	-	83.3	-	-	-	90.0	-	-	-
Marital status, % married	75.9	-	-	-	76.7	-	-	-	83.3	-	-	-	83.3	-	-	-

on a 10-point scale, 8) current participation in regular aerobic exercise, and 9) biofeedback training within the past year.

In order to recruit study participants, 916 medical charts were reviewed. Of these, 240 potential subjects meeting the inclusion criteria by chart review and with current addresses were contacted. Seventy persons indicated that they were not interested in participating; another 51 did not meet inclusion criteria. One hundred nineteen subjects were recruited and entered into the research project. Of these subjects, 109 (92%) participated in the 6-week posttreatment followup, 100 (84%) participated in the 3-month followup, 103 (87%) participated in the 1-year follow-up, and 101 (85%) participated in the 2-year followup. Of the 18 (15%) subjects who dropped out, 7 cited personal reasons, 4 cited problems with their work schedules, 3 moved, 2 cited health problems, and 2 cited an increase in pain. The total number of dropouts for the attention control, biofeedback, exercise, and combination groups were 3, 4, 4, and 7, respectively. Dropout rates across the 4 groups were not significantly different from each other,  $n = 119$ ,  $\chi^2(3) = 2.30$ ,  $P = 0.51$ .

There were 108 women and 11 men enrolled in the study. Among the women, 98, 90, 92, and 90 completed the posttreatment, 3-month, 1-year, and 2-year followups, respectively. Among the men, all 11 completed all followups, except for the 3-month followup which included 10 men. Subjects' mean age was 43.98 (SD 9.6) years; mean years of education was 13.3 (SD 2.5). Mean socioeconomic status (as measured by the Hollingshead index) was 38.7 (SD 15.7), with a possible range of 11 to 77. Subjects had an average FMS symptom duration (since onset of first symptoms) of 11.5 (SD 9.3) years. Average

duration since diagnosis of FMS was 2.7 (SD 2.9) years (see Table 1 for demographics by group).

**Procedures.** Informed consent was obtained for all study participants. Subjects consented to be randomly assigned to an education/rehabilitation intervention for FMS. In order to avoid potential bias, subjects were not told specific details about each of the 4 different groups.

The interventions for all 4 groups (3 experimental and one control) involved two phases: 1) a 6-week individual training phase and 2) a 2-year group maintenance phase. Assessments were conducted 5 times during the study: prior to training (pretreatment), immediately after the 6-week individual training phase (posttreatment), and 3 months, 1 year, and 2 years following training. During the individual training phase, subjects were seen once weekly for sessions ranging from 1.5 to 3 hours. Subjects were instructed to practice at least two additional times each week. During the maintenance phase, subjects met in groups once a month for an hour. Training sessions for each subject and for all conditions were conducted by the study trainers. Study trainers were bachelor and master's level persons with 1-5 years' experience who followed the study protocols.

Each assessment period was conducted during a single afternoon to control for diurnal fluctuation, and at a time other than the training or maintenance session. Subjects received a tender point exam by a trained physician (RC or DRK) who was not aware of the treatment condition. Physician contact was restricted to physical examinations in order to maintain blindness. Subjects were videotaped to assess pain behaviors. In addition, subjects completed

questionnaires including relevant demographic, medical, and psychological information.

Physician-referred subjects in the study remained under the care of their original physicians. No medication changes were made as a part of this study; however, subjects reported medication usage at each assessment appointment. Changes in medication usage across time were analyzed because of the potentially confounding effect on the outcome measures.

**Intervention groups.** *Biofeedback/relaxation training group.* Subjects (pretreatment  $n = 29$ ; posttreatment  $n = 27$ ; 3-month followup  $n = 23$ ; 1-year followup  $n = 26$ ; 2-year followup  $n = 25$ ) were taught cognitive and muscular relaxation strategies, as well as applications of these strategies to daily living. This intervention included didactics, self-monitoring, homework assignments, practice, and electromyogram biofeedback training to reduce trapezius muscle tension.

*Exercise group.* Subjects (pretreatment  $n = 30$ ; posttreatment  $n = 28$ ; 3-month followup  $n = 26$ ; 1-year followup  $n = 26$ ; 2-year followup  $n = 26$ ) participated in the following basic components: 1) active range of motion exercises, 2) specific strengthening exercises, 3) low to moderate intensity aerobic exercise (walking at 60% to 70% of the subject's age-predicted submaximal heart rate), 4) proper posture and body mechanics instruction, and 5) instruction on the use of heat, cold, and massage.

*Combination biofeedback/exercise group.* These subjects (pretreatment  $n = 30$ ; posttreatment  $n = 26$ ; 3-month followup  $n = 24$ ; 1-year followup  $n = 24$ ; 2-year followup  $n = 23$ ) participated in both the exercise and the biofeedback/relaxation training interventions.

*Educational/attention control group.* In order to control for attention and time with a trainer, the attention control program was developed. Subjects in this group (pretreatment  $n = 30$ ; posttreatment  $n = 28$ ; 3-month followup  $n = 27$ ; 1-year followup  $n = 27$ ; 2-year followup  $n = 27$ ) received educational information regarding the diagnosis and treatment of FMS as well as more general "health topics" information. Educational materials included Arthritis Foundation information on FMS. Practical medical information was discussed, but no specific problem-solving strategies were taught. Sackett and Haynes (19) concluded that information alone does not produce a significant impact on health behavior. Therefore, no significant improvements in symptom outcome measures were expected with this attention control intervention.

**Credibility check.** Credibility of the interventions was assessed using a 4-item questionnaire rated on a 7-point scale as described by Borkovec and Nau (20). Using a Kruskal-Wallis test for each item, there was only one significant difference among the groups that occurred at the 1-year followup on the first question ( $P = 0.04$ ). Random error may account for this result, since there were no other significant differences among the groups for any of the other phases of the study (the other 19  $P$  values  $> 0.20$ ) (Table 2). Therefore, the 4 interventions appeared to be equally credible.

**Validity check on the exercise intervention.** As a validity check on the effectiveness of the exercise intervention, measures of flexibility, strength, and exercise tolerance (Rockport Fitness Walking Test) were assessed at pre- and posttreatment, 18-month, and 2-year followup for the exercise and the combination groups. Most measures were significantly improved for both groups at followup periods when compared with the pretreatment scores, indicating that the exercise intensity and adherence to the exercise program were adequate to result in improvements in flexibility, strength, and exercise tolerance (Table 3).

**Measures.** *Tender Point Index (TPI).* The TPI is a behavioral response measuring a subject's reaction to the tender point exam. Upon palpation at each tender point site, reactions were rated on a 5-point scale (0 = no hurt/pain to 4 = patient untouchable/withdrawal without palpation). The TPI was calculated for each subject by dividing the total score by 20 to obtain an average score for each site (18).

*Myalgic scores.* Myalgic scores were obtained from the tender point exam by summing dolorimeter (1.54 cm<sup>2</sup> cork; Chatillon Instruments, Kew Gardens, NY) values from the subject's right side for each of the 6 sites, following the procedure outlined in the multicenter criteria study (18). Dolorimeter values for each site can range from 0 to 9; myalgic scores can range from 0 to 54.

*Physician's rating of disease severity.* After conducting the tender point exam, the physician rated the severity of the subject's fibromyalgia by marking a 10-cm line anchored with the endpoints "absent" and "very severe."

*Visual analog scale (VAS).* The VAS allowed subjects to select a point along a 10-cm line to describe their pain on a continuum from "no pain" to "pain as bad as it could be." Adequate reliability and validity for the VAS have been reported (21-23).

*Pain behavior observation method.* Keefe and Block (24) originally developed a behavior rating system for use with low back pain patients. Each subject

Table 2. Means (SD) of credibility questionnaire across time by treatment group

	Biofeedback				Exercise				Combination				Attention Control			
	Post-treatment n = 27	3-month followup n = 23	1-year followup n = 26	2-year followup n = 25	Post-treatment n = 28	3-month followup n = 26	1-year followup n = 26	2-year followup n = 26	Post-treatment n = 26	3-month followup n = 24	1-year followup n = 24	2-year followup n = 23	Post-treatment n = 26	3-month followup n = 27	1-year followup n = 27	2-year followup n = 27
Do you think that this treatment program seems logical in its approach to managing fibromyalgia?	5.7 (1.3)	5.2 (1.8)	5.3 (1.3)	5.0 (1.7)	5.9 (1.2)	5.5 (1.4)	5.5 (1.2)	5.3 (1.6)	5.9 (1.6)	5.6 (1.5)	5.8 (1.6)	5.6 (1.6)	5.2 (1.8)	5.0 (1.6)	4.7 (1.6)*	4.7 (1.9)
How confident are you that this treatment program will be successful in helping you manage your fibromyalgia? How confident would you be in recommending this treatment program to a family member or friend who also has problems with fibromyalgia?	5.4 (1.4)	4.8 (1.9)	5.0 (1.3)	4.8 (1.9)	5.9 (1.3)	5.2 (1.5)	5.2 (1.5)	4.9 (1.9)	5.5 (1.7)	5.4 (1.5)	5.4 (1.8)	5.2 (1.8)	4.9 (1.8)	5.0 (1.5)	4.7 (1.8)	4.7 (1.8)
Do you feel this treatment program will have a positive lasting effect for more than 6 months?	5.8 (1.4)	5.4 (1.9)	5.9 (1.6)	5.3 (1.8)	6.2 (1.3)	5.7 (1.6)	5.7 (1.5)	5.1 (2.1)	6.0 (1.5)	6.0 (1.5)	5.9 (1.8)	5.7 (2.1)	5.6 (1.9)	5.4 (1.4)	5.6 (1.7)	5.3 (1.9)
Do you feel this treatment program will have a positive lasting effect for more than 6 months?	5.7 (1.4)	5.0 (1.9)	5.4 (1.7)	5.0 (1.9)	5.9 (1.2)	5.3 (1.6)	5.5 (1.4)	5.0 (1.8)	5.7 (1.6)	5.7 (1.7)	5.6 (1.8)	5.7 (2.0)	5.4 (2.0)	5.4 (1.5)	5.2 (1.8)	5.3 (2.0)

\*P = 0.04.

Table 3. Medians of physical fitness measurements across time by treatment group

	Exercise				Combination			
	Pre-treatment	Post-treatment	18-month followup	24-month followup	Pre-treatment	Post-treatment	18-month followup	24-month followup
Rockport Walking Test, minutes per mile	17.1 (n = 22)	16.4* (n = 22)	16.6 (n = 13)	16.8 (n = 17)	18.3 (n = 27)	17.2† (n = 23)	15.9* (n = 11)	15.9† (n = 13)
Trunk sit and reach, inches	3.5 (n = 25)	7.8† (n = 26)	8.0 <sup>‡</sup> (n = 15)	7.0‡ (n = 19)	3.4 (n = 28)	5.9† (n = 24)	7.5 <sup>‡</sup> (n = 11)	6.9* (n = 14)
Curl-ups, number in 30 seconds	8.0 (n = 25)	14.0† (n = 25)	16.0† (n = 15)	20.0† (n = 16)	9.0 (n = 26)	12.0† (n = 23)	14.0† (n = 11)	15.5† (n = 14)
Over and under shoulder reach, inches between fingertips, 0 = fingertips touching	3.4 (n = 25)	2.2* (n = 26)	1.0 (n = 15)	3.3 (n = 18)	4.4 (n = 29)	3.3‡ (n = 25)	2.8 (n = 11)	3.9 (n = 15)
Shoulder blade press, nose touching wall, inches	9.3 (n = 25)	10.0 (n = 26)	10.4† (n = 15)	10.5† (n = 18)	9.8 (n = 29)	10.0‡ (n = 25)	11.5† (n = 11)	10.6‡ (n = 15)

\*  $P \leq 0.05$  versus pretreatment.†  $P \leq 0.001$  versus pretreatment.‡  $P \leq 0.01$  versus pretreatment.

was videotaped for 10 minutes while performing a standardized sequence of movements composed of 1- and 2-minute sitting/standing periods, and two 1-minute reclining/walking periods (24,25). Sequence order was randomized. Two trained independent raters, unaware of treatment assignment, coded the tapes for specific pain behaviors such as guarding, bracing, rubbing, grimacing, sighing, and stretching. Interrater kappa coefficients ranged from 0.64 (grimacing) to 0.98 (rubbing) (mean 0.88, SD 0.13); percentage of agreement ranged from 98.4% to 99.5% (26).

**Arthritis Impact Measurement Scales (AIMS).** The AIMS provide a reliable assessment of 9 health status variables (27,28). The Physical Activity subscale has been found to have adequate internal consistency and validity among a fibromyalgia sample (29) and was used in this study as a measure of functional activity.

**Symptom Checklist-90-Revised (SCL-90-R).** This 90-item checklist reflects the presence or absence of psychologic symptoms. Each item is rated on a 5-point scale. Adequate test-retest reliability and internal consistency have been documented (30). The Global Severity Index (GSI) was used as a measure of overall psychologic distress.

**Center for Epidemiologic Studies-Depression Scale (CES-D).** Depression was measured using the CES-D, a 20-item scale designed to measure depressive symptoms. Subjects rated on a 4-point scale the frequency with which they experienced each of 20 symptoms. A total score was calculated by summing

the individual items. Adequate test-retest reliability, internal consistency, and validity for the CES-D have been demonstrated (31,32).

**Self-efficacy.** Self-efficacy was assessed using the Arthritis Self-Efficacy Scale developed by Lorig et al (33). This measure includes 3 subscales: 1) self-efficacy for function, 2) self-efficacy for pain management, and 3) self-efficacy for controlling other arthritis symptoms. Both construct and concurrent validity of this scale have been demonstrated (33).

**Sleep.** Sleep problems were assessed by 4 questions on the medical information form. Subjects rated the following 4 sleep problems during the last month: "difficulty falling asleep," "waking tired," "waking frequently," and "sleeping poorly." Each problem was assessed on a 4-point rating scale ranging from "never or rarely" to "almost always." The total sleep score ranged from 0 to 12.

**Data analyses.** There were 5 phases of the data analyses. First, normality tests were performed for each study variable. Second, groups were compared at pretreatment using Kruskal-Wallis tests for continuous variables and chi-square tests for categorical variables to look for baseline differences. Third, to look specifically for the between-group differences, one-way (group) nonparametric analysis of covariance procedures (ANCOVA) (34) were performed using posttreatment data, covarying on the pretreatment measures. The same tests were employed using

Table 4. Medians of pretreatment, posttreatment, 3-month, 1-year, and 2-year followup outcome variables by

	Biofeedback					Exercise				
	Pretreatment n = 29	Posttreatment n = 27	3-month n = 23	1-year n = 26	2-year n = 25	Pretreatment n = 30	Posttreatment n = 28	3-month n = 26	1-year n = 26	2-year n = 26
Tender Point										
Index, range										
0-4	1.5	1.2 (-0.2)*	1.3 (0.1)	1.6 (0.1)	1.4 (-0.1)	1.6	1.3 (-0.2)*	1.4 (0)	1.5 (0.1)	1.5 (0.1)
Missing										
observations	1	-	2	3	7	-	-	-	2	3
Myalgic score,										
range 0-54	20.0	19.0 (1)	20.6 (1)	19.3 (2.9)	21.5 (2.5)	15.7	17.4 (1.3)	18.0 (1)	16.8 (1.3)	21.5 (5.2)†
Missing										
observations	-	-	1	2	6	-	-	-	2	3
Disense severity	5.7	4.7 (-1)†	5.3 (-0.2)	4.9 (-0.6)†	5.4 (-0.4)	5.6	5.0 (-1)‡	5.4 (-0.5)	5.3 (-0.6)	5.2 (-0.6)
Missing										
observations	-	-	1	2	6	-	-	-	2	3
Visual analog										
scale	5.0	3.6 (-2.3)‡	5.2 (-0.2)	5.0 ( 1.1)	5.2 ( -1.1)	6.3	4.6 (-1.1)†	5.4 (-0.8)‡	5.4 (-0.9)	5.5 (-1.2)‡
Pain behavior										
total	5.0	4.0 (-2)‡	2.5 (-1)†	4.0 (-1)‡	2.5 (-0.5)	4.0	4.0 (-1)	2.0 (-1)§	2.0 (-2)‡	4.0 (0)
Missing										
observations	-	-	1	2	7	-	-	-	2	3
Physical activity	6.0	6.0 (0)	6.0 (0)	6.0 (0)	6.0 (0)	4.0	4.0 (0)*	4.0 (0)*	4.0 (0)*	4.0 (0)*‡
Missing										
observations	-	-	-	-	-	-	-	-	-	-
Global Severity										
Index	69.0	64.0 (-3)§	65.0 (-2)	64.0 (-3)	64.0 (-1)	72.5	65.0 (-2)†	65.5 (-3)‡	67.0 (-4.5)‡	65.5 (-2.5)
Missing										
observations	-	-	-	-	-	-	-	-	-	-
CES-D¶	16.0	11.0 (-1)	10.0 (-2)	10.0 (-1.5)	10.0 (-2)‡	15.0	11.5 (-4)	13.5 (-2.5)	11.0 (-3.5)	11.5 (-3.5)
Self-efficacy										
(function)	74.4	84.4 (7.8)‡	81.1 (5.0)	83.3 (1.1)	85.6 (0)	86.1	88.3 (9.4)*§	87.0 (2.8)*‡	90.0 (3.9)*‡	89.4 (4.4)
Self-efficacy										
(pain)	46.0	62.0 (14)§	58.0 (8)†	57.0 (11)†	52.0 (12)†	48.0	58.0 (13)§	56.0 (6)§	55.0 (7)‡	55.0 (7)
Self-efficacy										
(other)	55.0	65.0 (3.3)†	58.3 (3.3)	61.7 (4.2)	56.7 (1.7)	50.0	63.3 (7.5)†	60.0 (5.8)	64.2 (8.3)†	63.3 (3.3)
Sleep	7.0*	5.0 (-1)‡	7.0 (0)	5.5 (-1.5)†	6.0 (-2)‡	8.0*	4.0 (-2)§	8.0 (0)	6.0 (-2)‡	7.5 (0)

\* Different versus attention control group based on post hoc analyses.

†  $P \leq 0.01$  versus pretreatment.‡  $P \leq 0.05$  versus pretreatment.§  $P \leq 0.001$  versus pretreatment.

¶ CES-D = Center for Epidemiologic Studies-Depression Scale.

3-month, 1-year, and 2-year followup data, while covarying on the pretreatment measures. The group factor consisted of 4 levels: biofeedback/relaxation, exercise, combination, and the attention control group. Post hoc multiple comparisons covarying on pretreatment scores were used to further assess significant ANCOVAs. Fourth, within-group comparisons were conducted using Wilcoxon signed rank tests to assess if there were significant changes from pre- to posttreatment followup scores for each group on each dependent variable. When more than one variable is used to measure a particular construct, the reader may want to adjust the significance level by dividing 0.05 by the number of variables measuring that construct (Bonferroni adjustment). Fifth, medication changes across time were evaluated post hoc. The Cochran's Q test was used to assess the presence or absence of a given medication in order to determine if medication changes occurred over time.

## RESULTS

**Normality tests.** Normality tests revealed that the data for many of the variables were skewed. Consequently, nonparametric methods (tests based on ranks) were employed.

**Group comparisons before treatment.** Kruskal-Wallis tests indicated no significant differences among the 4 groups on age, years of education, or socioeconomic status. Chi-square tests revealed no significant differences among the groups on the variables of gender, employment status, or medication usage (see Table 1).

There was only one significant pretreatment difference between the groups at baseline for the 12 dependent variables examined in the study. The attention control group had lower sleep scores

treatment group (median change from pretreatment using only subjects with both pre- and posttreatment values)

Combination					Attention control				
Pretreatment n = 30	Posttreatment n = 26	3-month n = 24	1-year n = 24	2-year n = 23	Pretreatment n = 30	Posttreatment n = 28	3-month n = 27	1-year n = 27	2-year n = 27
1.1	1.0 (0)*	1.1 (-0.1)*	1.0 (0)	1.1 (0.3)‡	1.2	1.4 (0.2)†	1.4 (0.2)‡	1.6 (0.3)‡	1.4 (0.2)‡
--	--	1	3	4	--	1	3	3	4
19.3	20.9 (0.5)	20.5 (0.8)	26.5 (3.5)	27.0 (7.5)§	20.6	21.0 (-1)	19.6 (-2.4)‡	20.8 (2.8)	24.5 (5.4)†
--	--	1	3	4	--	1	3	3	4
5.3	4.4 (-0.4)‡	4.6 (-0.3)	3.5 (-0.7)‡	4.7 (-0.1)	5.4	5.2 (0.1)	5.6 (0.3)	5.0 (-0.6)	4.6 (-0.3)
--	--	1	3	4	--	1	3	3	4
5.0	4.6 (-0.9)‡	3.2 (-1.1)	5.0 (0.1)	5.8 (0.4)	5.9	5.3 (-0.5)	5.8 (-0.5)	5.9 (-0.3)	5.4 (-0.6)
7.0	3.0 (-1.5)	2.0 (-4)§	3.0 (-2)‡	4.0 (-2.9)‡	3.4	5.0 (1)	3.0 (0)	2.0 (0)	3.0 (1)
--	--	1	3	5	--	1	4	3	5
6.0	4.0 (-1)*‡	5.0 (0)	4.0 (0)*‡	6.0 (0)‡	6.0	6.0 (0)	6.0 (0)	6.0 (0)	6.0 (0)
--	--	--	--	--	--	1	--	--	--
69.5	65.0 (-3.5)	64.0 (-2)†	63.5 (-2)	65.0 (-3)‡	63.5	65.0 (0)	65.0 (0)	65.0 (2)	67.0 (-1)
--	--	--	--	--	--	1	--	--	--
13.5	10.5 (-1)	14.0 (-3)‡	11.5 (-1.5)	11.0 (-1)	12.5	13.0 (0)	13.0 (3)	11.0 (-2)	12.0 (-2)
67.3	66.6 (7.4)*‡	65.2 (10)**	68.9 (5.6)*†	63.3 (5.6)‡	67.8	74.4 (0)	73.3 (-1.1)	77.0 (-2.2)	63.3 (1.1)
45.0	57.0 (7)‡	61.0 (10.7)†	56.0 (8)‡	60.0 (8)‡	47.0	56.0 (8)	56.0 (0)	48.0 (-2)	50.0 (4)
50.8	57.5 (2.5)	60.8 (12.8)‡	54.2 (5.8)	60.0 (10)	63.3	58.3 (0)	60.0 (-2.5)	58.3 (-5)	53.3 (-3.3)
7.0	4.5 (0)	6.0 (-1)	5.5 (-0.5)	5.0 (0)	5.5	5.0 (0)	5.0 (0)	6.0 (0)	6.0 (0)

(fewer difficulties with sleep) at baseline than did the biofeedback and exercise treatment groups,  $\chi^2(3, n = 119) = 7.72, P = 0.05$  (Table 4).

**Effects of the interventions on the Tender Point Index.** The nonparametric ANCOVAs revealed significant between-group differences for the TPI score at posttreatment and at 3-month followup only (see Table 5 and Figure 1). Post hoc comparisons revealed that all 3 treatment groups had improved TPI scores, relative to the attention control group (see Table 4) at posttreatment. This finding was maintained only for the combination group at 3-month followup. Significant within-group differences reflecting greater impairment were found for the attention control group at posttreatment and at all 3 followup periods.

**Effects of the interventions on the myalgic score.** Although there was one significant between-group difference at the 2-year followup on myalgic scores, post

hoc analyses revealed no differences between any of the treatment groups and the attention control group. Statistically significant within-group differences for the attention control group reflected impairment at the 3-month followup and improvement at the 2-year followup. Statistically significant within-group differences for the exercise and combination groups at the 2-year followup reflected improvement.

**Effects of the interventions on the disease severity measure.** There were no significant between-group differences for the disease severity measure. However, there were significant within-group differences reflecting improvements for the biofeedback and the combination groups at posttreatment and 1-year followup, and for the exercise group at posttreatment.

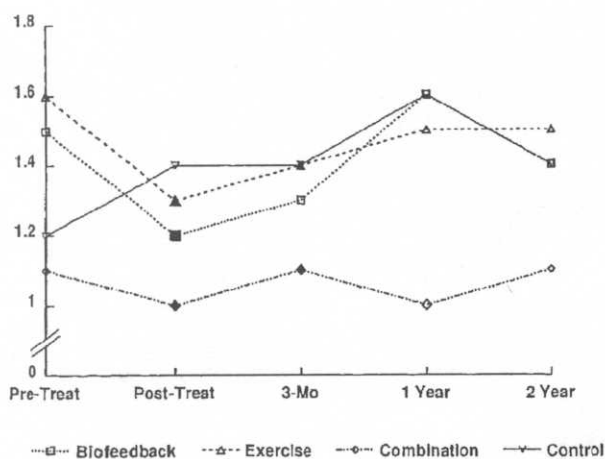
**Effects of the interventions on the self-reported pain measure (VAS).** There were no significant between-group differences for the self-reported

**Table 5.** Treatment group effects for dependent measures at posttreatment, 3-month followup, 1-year followup, and 2-year followup (covaried on pretreatment scores)

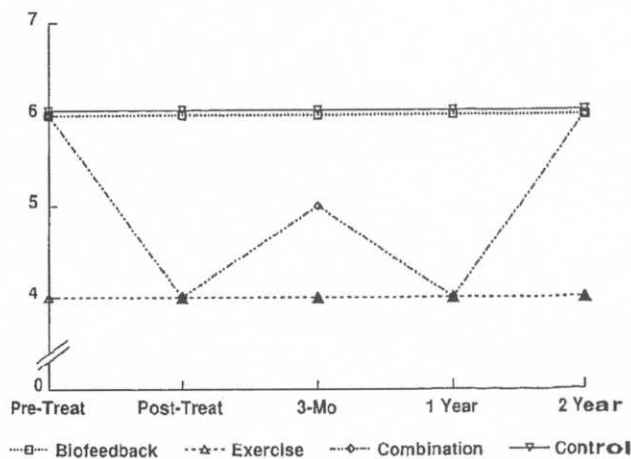
	Posttreatment		3-month followup		1-year followup		2-year followup	
	$\chi^2(3)$	<i>P</i>	$\chi^2(3)$	<i>P</i>	$\chi^2(3)$	<i>P</i>	$\chi^2(3)$	<i>P</i>
Tender Point Index	10.9	0.01	8.5	0.04	7.2	0.07	2.2	0.53
Myalgic score	1.8	0.62	4.5	0.22	4.9	0.18	7.7	0.05
Disease severity	5.3	0.15	2.8	0.42	4.2	0.24	0.1	0.99
Visual analog scale	3.8	0.29	3.4	0.33	0.4	0.93	4.4	0.22
Pain behavior total	2.5	0.48	2.5	0.47	2.6	0.45	4.6	0.20
Physical activity	8.3	0.04	3.0	0.05	13.1	0.004	11.0	0.01
Global Severity Index	6.9	0.07	1.4	0.71	4.3	0.23	1.2	0.75
Center for Epidemiologic Studies-Depression	3.1	0.37	2.0	0.56	0.4	0.93	2.2	0.53
Self-efficacy (function)	11.9	0.008	14.2	0.003	15.2	0.002	5.3	0.15
Self-efficacy (pain)	5.2	0.16	4.3	0.23	6.8	0.08	3.2	0.36
Self-efficacy (other)	4.2	0.24	3.4	0.33	6.2	0.10	3.7	0.29
Sleep	3.7	0.30	2.1	0.55	2.2	0.52	3.8	0.28

pain measure. However, significant within-group differences were found at posttreatment for all 3 treatment groups, reflecting improved pain scores. Median scores improved 38%, 27%, and 8%, for the biofeedback, exercise, and combination groups, respectively. The significant within-group difference was maintained for the exercise condition at the 3-month and 2-year followup, with median score improvements of 14% and 13%, respectively.

**Effects of the interventions on the pain behavior measure.** There were no significant between-group differences for the pain behavior measure. Significant within-group differences reflecting improvements were found for the biofeedback group at posttreatment, for all 3 treatment groups at 3-month and 1-year followups, and for the combination group at the 2-year followup. Reductions in median total pain behaviors ranged from 20% (biofeedback) to 71% (combination).



**Figure 1.** Medians of pretreatment (Pre-Treat), posttreatment (Post-Treat), 3-month (3-Mo), 1-year, and 2-year followup for the biofeedback, exercise, combination, and attention control groups on the Tender Point Index. Shaded symbols reflect  $P \leq 0.05$  when the specific group is compared with the attention control group, after covarying on pretreatment scores.



**Figure 2.** Medians of pretreatment (Pre-Treat), posttreatment (Post-Treat), 3-month (3-Mo), 1-year, and 2-year followup for the biofeedback, exercise, combination, and attention control groups on physical activity measures. Shaded symbols reflect  $P \leq 0.05$  when the specific group is compared with the attention control group, after covarying on pretreatment scores.

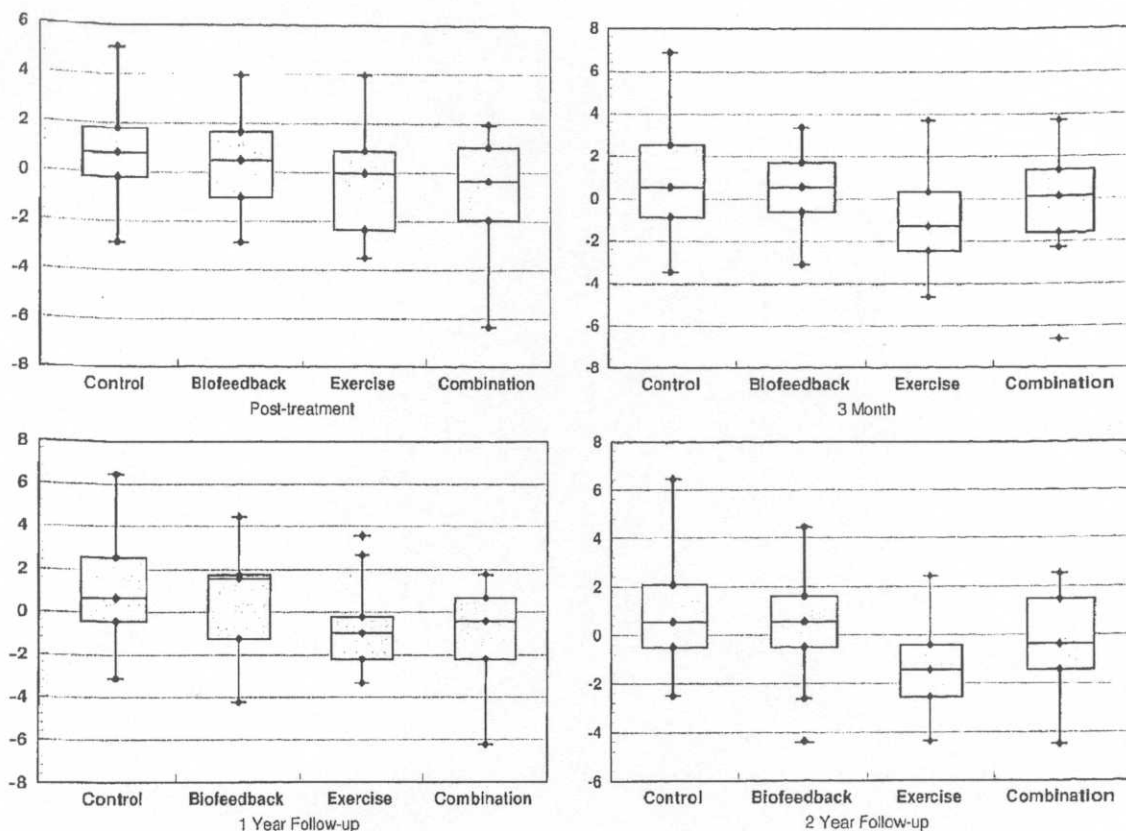


Figure 3. Box plots of residual scores at posttreatment, 3-month, 1-year, and 2-year followup for the physical activity measures.

**Effects of the interventions on the physical activity measure.** There were significant between-group differences for the physical activity measure at post-treatment and at all followup periods (Table 5 and Figure 2). Post hoc comparisons revealed that the exercise and combination groups had scores reflecting improved physical activity levels relative to the attention control group at posttreatment and at most of the followup periods. The ANCOVAs and post hoc comparisons take into account the covariate and the distribution of scores, not just the medians. In this case, the median scores for the groups changed little, but the distribution of these scores when adjusted for the baseline score changed significantly (see the box plots for these residual scores in Figure 3). Significant within-group differences reflecting improvements in physical activity were found for the combination group at post-treatment, 1-year, and 2-year followup periods, and for the exercise group at the 2-year followup. No significant within-group differences were found for the biofeedback or attention control groups.

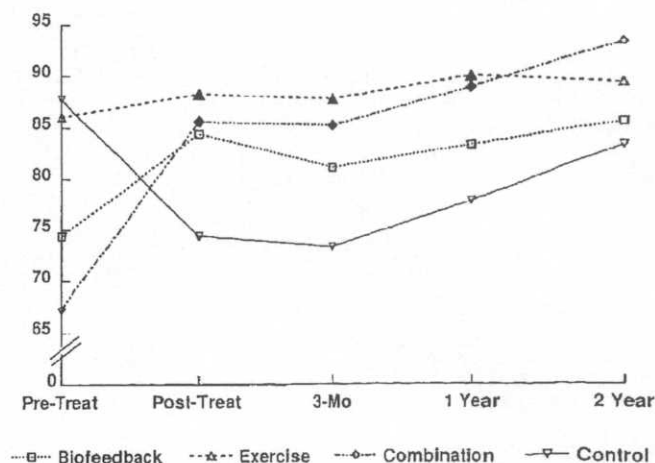


Figure 4. Medians of pretreatment (Pre-Treat), posttreatment (Post-Treat), 3-month (3-Mo), 1-year, and 2-year followup for the biofeedback, exercise, combination, and attention control groups on self-efficacy for function. Shaded symbols reflect  $P \leq 0.05$  when the specific group is compared with the attention control group, after covarying on pretreatment scores.

**Effects of the interventions on the Global Severity Index of the SCL-90-R.** There was no significant between-group difference for the GSI. However, significant within-group differences were found for all 3 treatment groups at posttreatment, reflecting improvement. These differences were maintained in the exercise group at the 3-month and 1-year followups, and in the combination group at the 3-month and 2-year followups.

**Effects of the interventions on the CES-D.** No significant between-group differences were found for the CES-D scores. Significant within-group differences were detected in the combination group at 3-month followup and in the biofeedback group at 2-year followup, both reflecting improvement. The median score for the biofeedback group improved 13% at 2-year followup.

**Effects of the interventions on the self-efficacy for function measure.** There were significant between-group differences on the self-efficacy for function measure at posttreatment, 3-month, and 1-year followups (Table 5 and Figure 4). Post hoc comparisons revealed that the exercise and combination groups had higher self-efficacy for function scores, reflecting improvement, relative to the attention control group at these 3 followup periods. Significant within-group differences on self-efficacy for function scores were found at posttreatment for all 3 treatment groups, reflecting improvements, and were maintained at 3-month and 1-year followups for the exercise and combination groups and at 2-year followup for the combination group.

**Effects of the interventions on the self-efficacy for pain measure.** No significant between-group differences were found on the self-efficacy for pain measure. However, all treatment groups showed significant within-group differences reflecting improvements from pretreatment levels. Both the biofeedback and combination groups had improved self-

efficacy for pain across all followup periods, with median score improvements ranging from 13% to 36%. The exercise group also improved at all phases except the 2-year followup.

**Effects of the interventions on the self-efficacy for other symptoms measure.** No significant between-group differences were found for the treatment groups. The biofeedback and exercise groups demonstrated significant within-group differences reflecting improvement at posttreatment, which was maintained for the exercise group at 1-year followup. In addition, the combination group improved at the 3-month followup.

**Effects of the interventions on the sleep measure.** There was no significant between-group difference for the sleep measure. Significant within-group differences reflecting improved sleep were found at posttreatment, 1-year, and 2-year followup for the biofeedback group. The exercise group improved at both posttreatment and 1-year followups. No significant changes were found for the combination group.

**Percentage of within-group differences across time.** Table 6 summarizes the percentages of dependent variables for each treatment group that were statistically significant across time. All significant within-group differences reflect improvements with the exception of myalgic scores, which were significantly more impaired at 2-year followup for the exercise, combination, and attention control groups. The total numbers of significant variables across time were 17 (35%), 19 (44%), and 24 (50%) for the biofeedback, exercise, and combination groups, respectively. The combination group resulted in the fewest statistically significant within-group differences at posttreatment and the most statistically significant within-group differences at 2-year followup.

**Post hoc medication analyses across time.** Percentages of participants utilizing medications in the biofeedback, exercise, combination, and attention control groups, respectively, included the following: analgesics (93%, 93%, 83%, 73%), antidepressants/tranquilizers (53%, 60%, 53%, 53%), sedatives/hypnotics (17%, 13%, 10%, 17%), and muscle relaxants (10%, 10%, 10%, 7%). There were no significant medication changes across time.

**Table 6.** Percentage of within-group differences across treatment groups and across time

	Posttreatment	3-month followup	1-year followup	2-year followup
Biofeedback	67	17	33	25
Exercise	67	42	50	25
Combination	50	50	42	67
Total	58	36	42	36

## DISCUSSION

First, this study found that all 3 of the treatment interventions resulted in enhanced self-efficacy for

function, replicating the Burckhardt et al study (11), which demonstrated that a clinical trial of education and physical training resulted in enhanced self-efficacy. Self-efficacy refers to the belief that one can competently cope with a challenging situation and has the ability to affect behavior (35). For example, people with high self-efficacy beliefs tend to persist with coping behaviors until successful. In contrast, individuals with low self-efficacy beliefs more quickly discontinue coping efforts because failure is anticipated.

Self-efficacy is an important predictor of pain and disease severity measures in the fibromyalgia population. For example, higher baseline levels of self-efficacy are associated with less baseline self-report pain (29), fewer pain behaviors (26), and less impairment on physical activities measures (29). In addition, higher pretreatment self-efficacy scores significantly predict higher posttreatment physical activity. Larger changes in self-efficacy significantly predict higher posttreatment levels for physical activity, and lower posttreatment levels for pain and disease severity (36).

In a recent critique of self-efficacy measures used in arthritis research (37), it has been suggested that the self-efficacy measure used in this research may not measure self-efficacy as proposed by Bandura (35), but may measure expectancies about outcome. Similarly, Lorig et al (33) and Smarr et al (38) suggested that the self-efficacy measure assesses non-helplessness, mastery, or personal control. Despite some controversy about the scale used in this study, the reason for the lack of concordance between other outcome variables and self-efficacy is not clear.

Second, the exercise and the combination groups obtained significant, although modest, improvements on the physical activity measure relative to the attention control group, which were maintained at followup. This finding is particularly important in light of the design of this exercise program as a moderate intensity home program. Subjects were instructed to not exceed 70% of maximum heart rate. This study indicates that a low to moderate intensity exercise program can result in physical improvements without exacerbating pain or discomfort in the fibromyalgia population. This type of exercise program resulted in a lower dropout rate than found with more intensive exercise programs (7,8).

Third, there were significant between-group differences on the tender point examination measure. This significant difference reflects a modest increase in impairment by the attention control group rather than improvements by the treatment groups, suggest-

ing that these interventions may prevent the development of increased tenderness.

Fourth, there were no significant between-group pre- to posttreatment differences on self-report pain, pain behavior, sleep, or psychological distress measures. Significant within-group effects for all 3 treatment groups reflected modest improvements on pain and psychological distress measures. Study participants as a group continued to have significant clinical symptoms of FMS, despite an apparent improvement in self-efficacy for managing these symptoms.

Fifth, only the combination group maintained improvements on the self-efficacy for function measure at 2-year followup. In addition, the percentage of within-group differences on the dependent measures was best maintained by the combination group at 2-year followup. Only studies that include a long-term followup phase may be able to detect an additive effect of a psychologically based and an exercise intervention.

There are limitations to this study. For example, Yunus' criteria for diagnosis were used because the more recent criteria recommended by the ACR were not available at the beginning of the study. However, the mean tender point count was 15, and 63% of the sample met the ACR criteria. In addition, the 6 weekly individual training sessions followed by monthly group maintenance sessions may have been inadequate to establish long-term adherence to the treatment programs. Similarly, the monthly group sessions may not have provided adequate intervention to maintain the initial treatment benefits. In the future, studies might incorporate longer initial interventions. Utilizing a dichotomous adherence measure, our research team found that people in the biofeedback condition and people who were older and better educated were more adherent to the study protocol (39). Research is also needed to develop methods to enhance long-term adherence and maintenance of self-directed behaviors.

In summary, this study demonstrated that biofeedback/relaxation training and structured exercise programs produce short- and long-term benefits for persons with FMS in the areas of self-efficacy, disease severity, and physical activity. With the exception of the self-efficacy scores, the improvements were modest. Future studies are needed to examine the relative benefits of exercise and psychologically based treatment interventions versus antidepressant medications, to examine the underlying mechanisms of treatment efficacy, and to improve the long-term effectiveness of behavioral treatment programs for people with fibromyalgia.

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