

# Group Exercise, Education, and Combination Self-management in Women With Fibromyalgia

## A Randomized Trial

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**Background:** Self-management has increasingly been recommended as part of standard care for fibromyalgia, a common, poorly understood condition with limited treatment options. Data that assess popular self-management recommendations are scarce. We evaluated and compared the effectiveness of 4 common self-management treatments on function, symptoms, and self-efficacy in women with fibromyalgia.

**Methods:** A total of 207 women with confirmed fibromyalgia were recruited from September 16, 2002, through November 30, 2004, and randomly assigned to 16 weeks of (1) aerobic and flexibility exercise (AE); (2) strength training, aerobic, and flexibility exercise (ST); (3) the Fibromyalgia Self-Help Course (FSHC); or (4) a combination of ST and FSHC (ST-FSHC). The primary outcome was change in physical function from baseline to completion of the intervention. Secondary outcomes included social and emotional function, symptoms, and self-efficacy.

**Results:** Improvements in the mean Fibromyalgia Impact Questionnaire score in the 4 groups were -12.7 for the ST-FSHC group, -8.2 for the AE group, -6.6 for the ST group, and -0.3 for the FSHC group. The ST-FSHC group demonstrated greater improvement than the FSHC

group (mean difference, -12.4; 95% confidence interval [CI], -23.1 to -1.7). The ST-FSHC (mean difference, 13.6; 95% CI, 2.3 to 24.9) and AE (mean difference, 13.1; 95% CI, 1.6 to 25.6) groups had similar improvements in physical function scores on the 36-Item Short-Form Health Survey. Bodily pain scores on the 36-Item Short-Form Health Survey improved in the ST-FSHC (14.8), AE (13.2), and ST (5.7) groups. Social function, mental health, fatigue, depression, and self-efficacy also improved. The beneficial effect on physical function of exercise alone and in combination with education persisted at 6 months.

**Conclusions:** Progressive walking, simple strength training movements, and stretching activities improve functional status, key symptoms, and self-efficacy in women with fibromyalgia actively being treated with medication. The benefits of exercise are enhanced when combined with targeted self-management education. Our findings suggest that appropriate exercise and patient education be included in the treatment of fibromyalgia.

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**F**IBROMYALGIA IS A PREVALENT multidimensional disorder with complex symptoms and relatively poor treatment outcomes.<sup>1-3</sup> Fibromyalgia is characterized by diffuse chronic pain for more than 3 months and bilateral sites of focal tenderness.<sup>4</sup> It is associated with fatigue, sleep dysfunction, stiffness, depression, cognitive disruption, and exercise intolerance.<sup>3</sup> The prevalence of fibromyalgia in the United States is estimated to be 3.4% in women and 0.5% in men<sup>5</sup> and is reported to be greater in individuals with other rheumatic conditions.<sup>6</sup> The causes and pathologic mechanisms of fibromyalgia are unknown. Current hypotheses center on atypical sensory processing in the central nervous system and dysfunction of skeletal muscle nociception and the hypothalamic-pituitary-adrenal axis.<sup>7-9</sup> Even with the recent approval of pregabalin by the Food and Drug Administration to treat fibromyalgia symptoms, pharmacotherapy is often insufficient to resolve persistent symptoms or improve functional limitations and quality of life.<sup>10-12</sup>

Nonpharmacologic treatments, primarily exercise and behavioral interventions, are increasingly recommended for the treatment of patients with fibromyalgia.<sup>1,13</sup> The number of randomized controlled trials of exercise or behavioral interventions in the fibromyalgia literature has increased dramatically in the past de-

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cade. These studies<sup>14-19</sup> have been summarized recently. Comparison among studies is limited by differences in the types of exercise, incomplete protocol descriptions and adherence rates, inconsistent outcome measures, small sample sizes, and high attrition rates. The literature comparing exercise, education, and combination interventions is thin and includes a variety of interventions and inconsistent outcomes.<sup>20-24</sup> These methodologic issues have been an obstacle to translating research findings into practical clinical recommendations. Therefore, the aim of this study was to evaluate and directly compare the effects of 4 common self-management interventions on well-established measures of functional status, symptom severity, and self-efficacy in women with fibromyalgia.

## METHODS

### STUDY DESIGN AND APPROVAL

The institutional review board at Beth Israel Deaconess Medical Center and the scientific advisory committee of its General Clinical Research Center approved this randomized trial. Each participant gave verbal consent before undergoing the telephone screen for eligibility and written informed consent at baseline assessment.

### PARTICIPANTS AND RECRUITMENT

Women 18 to 75 years of age with a confirmed diagnosis of fibromyalgia<sup>4</sup> were recruited directly from physician practices. A descriptive brochure was placed in large rheumatology practices throughout Boston and surrounding communities. Additionally, an investigator (D.L.G.) who specializes in fibromyalgia evaluation and care included a description of the study in mailings to approximately 2500 of his patients. Letters were also sent to approximately 500 primary care physicians in Boston and surrounding communities. A telephone screen that included medical history and exercise habits<sup>25</sup> was administered to assess a person's eligibility.

Participants met the American College of Rheumatology criteria for fibromyalgia<sup>4</sup>; diagnosis was confirmed by the primary care physician of each participant. For participants in the care of a rheumatologist, we required agreement on the fibromyalgia diagnosis between physicians for enrollment. To accomplish the aims of this study and ensure participant safety, we excluded individuals with medical conditions that limited a person's ability to perform the exercise protocol or for whom moderate-level exercise was contraindicated.

### RANDOMIZATION

Participants were randomly assigned to 1 of 4 groups: (1) aerobic and flexibility exercise (AE); (2) strength training, aerobic, and flexibility exercise (ST); (3) the Arthritis Foundation's Fibromyalgia Self-Help Course (FSHC); or (4) a combination of ST and FSHC (ST-FSHC). Members of the hospital's Biometrics Center not involved in the study used a computer program that generated single-page listings of random group assignment. Individual pages were placed in opaque envelopes, sealed, numbered sequentially, and stored in a locked cabinet. We stratified randomization by level of functional status indicated by a score of less than 40 or 40 or higher on the Fibromyalgia Impact Questionnaire (FIQ) to reduce the chance of an imbalance in this primary outcome variable.

## INTERVENTIONS

All interventions were offered at 3 sites: 2 community fitness facilities outside Boston and the hospital wellness center.

### EXERCISE

Both exercise programs in this study involved approximately 60 minutes of activity per session. Each session began with a brief warm-up of walking on a treadmill at a comfortable pace and then progressed to a self-determined level of moderate effort for a predetermined amount of time.<sup>26</sup> All participants, regardless of fitness level, began with 5 minutes of walking and increased a maximum of 2 to 4 minutes weekly following a predetermined progression. The AE group progressed to a total of 45 minutes of walking. The ST group reached a maximum of 20 minutes of treadmill walking followed by 25 minutes of strength training movements. The 6 strength training exercises involved a combination of machines (chest press, seated row, and leg press) (Life Fitness, Schiller Park, Illinois), hand weights (standing biceps curl and triceps kickback), and calisthenics (modified abdominal crunches). Each participant began with 1 set of 6 repetitions at a resistance level the participant could perform easily with proper technique: seated row (15 lb), leg press (50% of the person's 1 repetition maximum), chest press (15-20 lb), and biceps curl and triceps kickback (1-5 lb based on demonstration of exercise technique after 3 instruction sessions). Resistance exercises progressed to 2 sets of 10 to 12 repetitions, and the participant determined when to increase the number of repetitions.<sup>26,27</sup> The final portion of each session for both exercise groups included flexibility exercises that involved primary body movements. The AE program represented the commonly recommended aerobic and flexibility exercise program, and the ST program included additional strength training movements.<sup>27</sup> The 2 exercise groups met twice weekly on different days of the week (ie, Monday and Wednesday vs Tuesday and Thursday) to avoid group contamination. Written instructions were provided to all participants to perform a third day of exercise on their own.

### EDUCATION

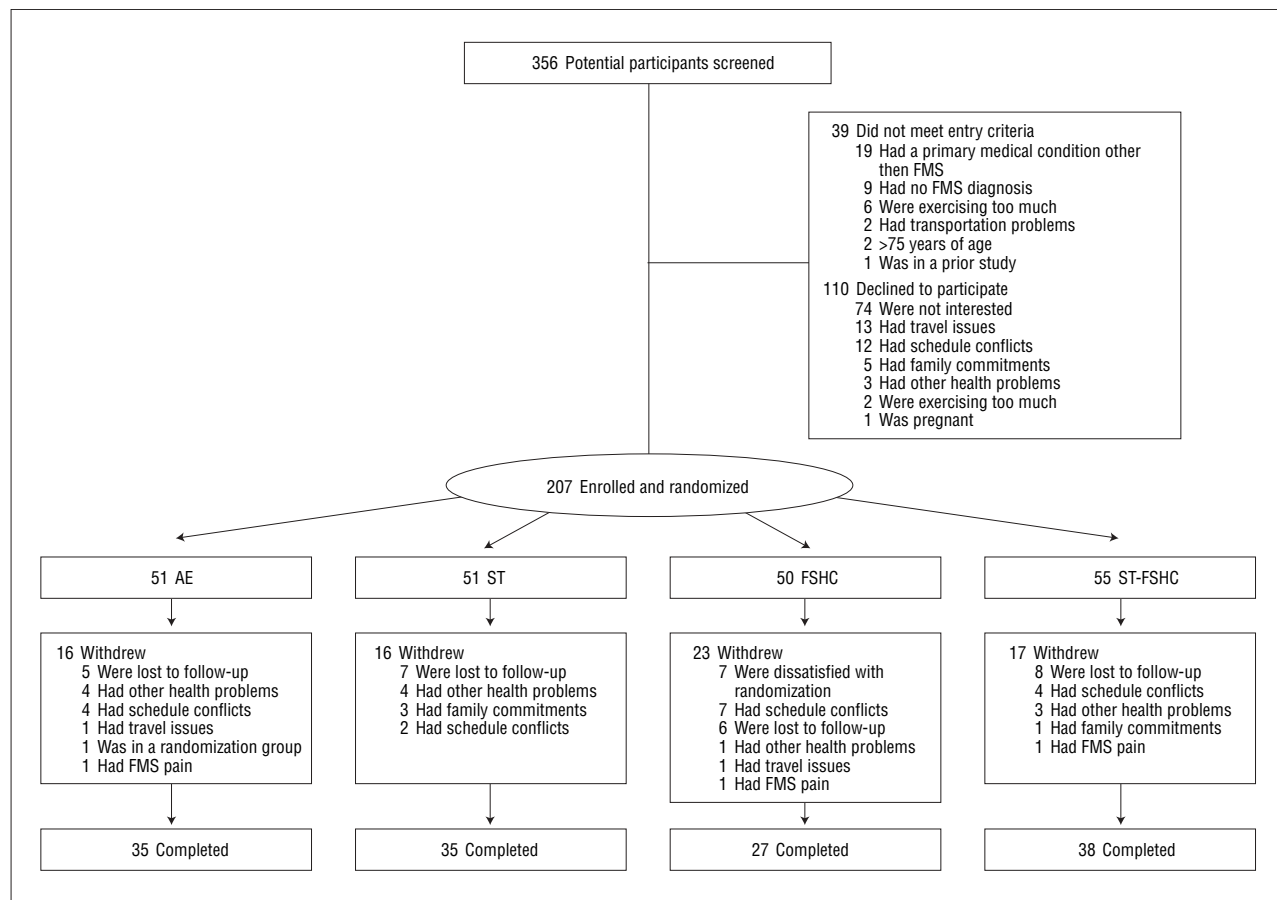
The FSHC is a 7-session program that teaches individuals with fibromyalgia about the condition and self-management skills. Materials promoted basic self-management techniques to accomplish daily activities and manage symptoms and suggested ways to incorporate wellness activities, including exercise, into daily life. Information was provided through a series of lectures (5-15 minutes) with facilitated group discussion and supplementary readings.<sup>28</sup> Sessions were 120 minutes long every 2 weeks. All FSHC instructors were certified by the Arthritis Foundation.

### COMBINATION

Participants assigned to the combination group (ST-FSHC) participated in both the ST and FSHC groups' activities.

### OUTCOMES

The primary outcome of this study was the change in physical function from baseline to completion of the 16-week intervention. We used 2 self-assessment instruments and 1 performance measure to quantify physical function. The FIQ is a valid, 10-item instrument that assesses physical function, common symptoms, and general well-being.<sup>29</sup> A change in the total score of 20% or greater was suggested to be clinically important.<sup>30</sup>



**Figure 1.** Enrollment, randomization, and retention of study sample. AE indicates aerobic and flexibility exercise; FMS, fibromyalgia syndrome; FSHC, Fibromyalgia Self-Help Course; ST, strength training, aerobic, and flexibility exercise; and ST-FSHC, a combination of ST and FSHC.

The physical function scale of the 36-Item Short-Form Health Survey (SF-36) was used as a generic measure of function.<sup>31</sup> This self-administered scale assesses health status in populations with musculoskeletal conditions.<sup>32</sup> The distance covered during the 6-minute walk test objectively assessed mobility, which was used as a proxy for physical function.<sup>27,33</sup>

Secondary outcome measures included fibromyalgia-related symptoms and self-efficacy. Symptoms were assessed using the visual analog scales of the FIQ, the bodily pain and vitality subscales of the SF-36, and the Beck Depression Inventory.<sup>34,35</sup> Self-efficacy is the confidence in one's ability to perform a particular behavior or task and is believed to be a determinant of fibromyalgia symptoms.<sup>36-38</sup> We adapted the Arthritis Self-Efficacy Scale<sup>39</sup> by replacing the term *arthritis* with *fibromyalgia* in the pain and other symptoms subscales<sup>40</sup> and used the original scoring algorithm.

Participants underwent all assessment measures in the General Clinical Research Center at Beth Israel Deaconess Medical Center. Testers masked to participant group assignment administered all tests. Upper and lower body muscle strength indicated whether exercise was performed at intensities sufficient to bring about expected changes in fitness between the 2 exercise interventions.<sup>27</sup>

### SAMPLE SIZE

Our previous exercise work in women with fibromyalgia resulted in mean±SD improvements in FIQ scores of approximately 8±4 points.<sup>27</sup> We hypothesized that education would have a similar effect as exercise and that the combined pro-

gram would be at least 5 points better than either of the single interventions, estimating an SD of 6. Allowing for 3 post hoc comparisons (ST-FSHC vs AE, ST, and FSHC), 31 participants completing the study in each group were required ( $\alpha = .0167$ , 2-sided) to achieve 90% power for a comparison of mean scores of 8 vs 13. We anticipated 30% attrition and rounded up to 50 participants per group.

### STATISTICAL ANALYSIS

Our primary analysis included participants who completed the intervention and were retested, regardless of their intervention adherence. Additionally, we performed an intention-to-treat analysis that included all 207 participants randomized to the 4 groups. We used the conservative approach of carrying forward the baseline value of variables in all participants who did not undergo a follow-up assessment. A mixed-model analysis using individuals with scores at all 3 time points was used to assess 6-month follow-up data of the primary outcome variables.

Normality testing on the changes from baseline to follow-up within each of the 4 groups was performed using the Shapiro-Wilk test<sup>41</sup> and other appropriate methods. Within-group change scores were evaluated using the paired *t* test or Kruskal-Wallis test as appropriate. Analysis of variance with Bonferroni adjustment for multiple comparisons was used to compare mean change scores across the 4 groups. Baseline values and demographic characteristics between completers and noncompleters in each of the 4 groups were compared with the 2-sample *t* test and Wilcoxon rank sum test for continuous variables and Fisher exact test for categorical variables. All analy-

**Table 1. Demographics of Participants Who Completed the Intervention<sup>a</sup>**

Demographic	AE	ST	FSHC	ST-FSHC
No. (%) of participants	35 (69)	35 (69)	27 (54)	38 (69)
Age, y	48 (11)	50 (11)	51 (12)	50 (11)
Height, cm	162 (6)	161 (6)	162 (6)	163 (6)
Weight, kg	75 (18)	76 (14)	75 (18)	78 (16)
BMI	29 (6)	30 (6)	29 (7)	29 (6)
Self-reported race, No. (%)				
White	29 (83)	32 (91)	25 (93)	35 (92)
African American	4 (11)	1 (3)	2 (7)	3 (8)
Other	2 (6)	2 (6)	0 (0)	0 (0)
Marital status, No.				
Married or living with significant other	23 (66)	23 (66)	15 (55)	21 (55)
Widowed, divorced, or separated	3 (8)	9 (26)	5 (19)	8 (21)
Single	9 (26)	3 (8)	7 (26)	9 (24)
Educational level, No.				
Postgraduate	8 (23)	14 (40)	11 (41)	8 (21)
College	13 (37)	9 (26)	5 (18)	11 (29)
Some college	8 (23)	11 (31)	8 (30)	10 (26)
High school	6 (17)	1 (3)	3 (11)	9 (24)
Years of diagnosis	5 (4)	6 (4)	6 (5)	6 (6)
No. of comorbidities	2 (1)	2 (2)	3 (2)	3 (2)

Abbreviations: AE, aerobic and flexibility exercise; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); FSHC, Fibromyalgia Self-Help Course; ST, strength training, aerobic, and flexibility exercise; ST-FSHC, a combination of ST and FSHC.

<sup>a</sup>Data are presented as mean (SD) unless otherwise indicated.

ses were performed with SAS statistical software, version 9.1 (SAS Institute Inc, Cary, North Carolina).

## RESULTS

### RECRUITMENT AND RETENTION OF PARTICIPANTS

Of 356 eligible women who were recruited between September 16, 2002, and November 30, 2004, 207 were enrolled and randomized. One hundred ten people who were eligible declined to participate, and 39 people did not meet the inclusion criteria. Primary reasons eligible people gave for not participating related to commuting to an intervention site and schedule conflicts (**Figure 1**). Of the 207 participants randomized, 135 (65%) completed the 16-week intervention period and underwent a follow-up assessment. There was 31% attrition in each of the 3 exercise groups and 46% in the FSHC group. Reasons for dropping out centered on health problems other than fibromyalgia and schedule conflicts with work or family (Figure 1). Seven of the 50 participants randomized to FSHC (14%) were dissatisfied with their group assignment and withdrew after the baseline visit. Participants who did not provide a reason for dropping were classified as lost to follow-up. Baseline characteristics of participants who completed (**Table 1**) and did not complete the intervention were similar except that dropouts from the FSHC group had a shorter time since diagnosis (3.3 vs 5.6 years;  $P = .05$ ).

### BASELINE CHARACTERISTICS

The typical participant was a white woman approximately 50 years of age, overweight, married, and well edu-

cated. She had 2 to 3 comorbidities and a diagnosis of fibromyalgia for approximately 6 years at the time of study enrollment.

### ADHERENCE AND SAFETY

Adherence, determined by class attendance, was similar among the 4 groups. The mean attendance rate, which included planned absences, was 73% for the AE group, 78% for the ST group, 77% for the FSHC group, and 78% for the ST-FSHC group. During the study period, no participant reported an exacerbation of fibromyalgia symptoms beyond normal flares, and there were no serious adverse events.

### FUNCTION

We used a combination of self-assessed (**Table 2**) and objective (**Table 3**) measures to evaluate the effects of the interventions on the primary outcome measure of physical function. All groups that participated in exercise showed greater improvement in function compared with the FSHC group. Among the 3 exercise groups, the ST-FSHC group demonstrated the greatest increases in all self-assessed outcome scores. Examination of the FIQ total score revealed a clinically and statistically significant improvement of 25% in the ST-FSHC group compared with 0% in the FSHC group (mean difference,  $-12.4$ ; 95% confidence interval [CI],  $-23.1$  to  $-1.7$ ). The AE (mean difference,  $-8.2$ ;  $P = .003$ ) and ST (mean difference,  $-6.6$ ;  $P = .02$ ) groups recorded within-group improvements before and after the 16 weeks. The ST-FSHC (mean difference, 13.6; 95% CI, 2.3 to 24.9) and AE (mean difference, 13.1; 95% CI, 1.6 to 25.6) groups had similar improvements in the SF-36 physical function scores after completion of the group in-

**Table 2. Self-assessed Measures of Function, Symptom Severity, and Self-efficacy<sup>a</sup>**

Time Point	AE (n=35)	ST (n=35)	FSHC (n=27)	ST-FSHC (n=38)
<b>FIQ</b>				
Total score				
Before	48.4 (11.2)	44.9 (9.3)	44.3 (11.1)	48.4 (12.2)
After	40.2 (15.1)	38.3 (12.9)	44.0 (15.2)	35.7 (13.5)
Change	-8.2 (14.6) <sup>b</sup>	-6.6 (12.9) <sup>c</sup>	-0.3 (9.9)	-12.7 (13.2) <sup>d,e</sup>
Pain				
Before	6.0 (2.1)	5.6 (2.1)	6.0 (2.1)	6.6 (2.1)
After	4.8 (2.5)	5.2 (2.0)	5.9 (2.2)	4.9 (2.4)
Change	-1.2 (2.4) <sup>b</sup>	-0.4 (2.7)	-0.1 (2.5)	-1.7 (2.1) <sup>d</sup>
Morning fatigue				
Before	7.3 (1.7)	7.6 (1.6)	6.8 (2.1)	7.3 (1.9)
After	6.4 (2.8)	6.9 (2.3)	6.9 (1.9)	6.3 (2.3)
Change	-0.9 (3.0)	-0.7 (2.1) <sup>c</sup>	0.1 (1.8)	-1.0 (2.3) <sup>c</sup>
Daily fatigue				
Before	7.7 (1.6)	7.0 (2.3)	6.9 (1.6)	7.2 (2.0)
After	6.6 (2.5)	6.6 (2.2)	7.2 (1.7)	6.0 (2.4)
Change	-1.1 (2.3) <sup>c</sup>	-0.4 (1.7)	0.2 (1.7)	-1.2 (3.1) <sup>c</sup>
Depressed				
Before	4.9 (2.9)	4.2 (2.9)	5.0 (2.4)	5.1 (2.7)
After	4.3 (3.0)	3.0 (2.5)	4.2 (2.8)	3.3 (2.6)
Change	-0.6 (3.0)	-1.2 (2.8) <sup>c</sup>	-0.7 (2.2)	-1.8 (3.0) <sup>d</sup>
Anxious				
Before	5.9 (2.7)	5.5 (2.9)	4.8 (2.7)	5.7 (2.6)
After	4.9 (2.7)	4.1 (3.0)	4.6 (2.9)	4.0 (2.5)
Change	-1.0 (2.7) <sup>c</sup>	-1.4 (2.8) <sup>b</sup>	-0.2 (2.4)	-1.7 (3.1) <sup>b</sup>
Stiffness				
Before	6.8 (2.1)	6.5 (2.4)	6.8 (2.3)	7.3 (2.0)
After	5.8 (2.5)	5.5 (2.7)	6.3 (2.2)	5.4 (2.5)
Change	-1.0 (2.8) <sup>c</sup>	-1.0 (2.9)	-0.5 (2.5)	-1.9 (2.9) <sup>d</sup>
<b>SF-36</b>				
Physical function				
Before	42.9 (19.1)	47.8 (23.0)	46.3 (23.9)	42.5 (18.9)
After	58.9 (20.3)	56.8 (19.6)	49.3 (23.9)	59.1 (19.1)
Change	16.1 (16.7) <sup>d,e</sup>	9.0 (15.1) <sup>b</sup>	3.0 (18.5)	16.6 (16.7) <sup>d,e</sup>
Social function				
Before	55.4 (27.8)	60.6 (29.2)	53.2 (29.3)	46.1 (27.1)
After	64.3 (28.6)	73.1 (26.5)	55.1 (35.1)	69.7 (27.1)
Change	8.9 (28.9)	12.5 (24.2) <sup>b</sup>	1.9 (24.7)	23.7 (34.2) <sup>d,e</sup>
Mental health				
Before	58.1 (23.6)	61.9 (21.0)	62.4 (19.8)	55.9 (19.9)
After	63.7 (23.0)	69.4 (18.7)	63.9 (24.8)	69.4 (18.0)
Change	5.6 (22.5)	7.5 (12.0) <sup>d</sup>	1.5 (18.5)	13.5 (21.9) <sup>d</sup>
Bodily pain				
Before	35.5 (17.3)	41.5 (18.2)	33.0 (17.5)	32.6 (17.3)
After	48.7 (21.4)	47.2 (18.4)	37.9 (20.4)	47.4 (19.7)
Change	13.2 (18.4) <sup>d</sup>	5.7 (16.0) <sup>c</sup>	4.8 (16.5)	14.8 (20.7) <sup>d</sup>
Vitality				
Before	23.1 (15.3)	27.4 (20.6)	27.6 (20.0)	22.9 (15.9)
After	34.6 (26.6)	34.4 (22.8)	30.0 (20.7)	40.6 (21.6)
Change	11.4 (23.0) <sup>b</sup>	7.1 (20.5)	2.4 (16.8)	17.7 (25.0) <sup>d,e</sup>
Role physical				
Before	13.3 (30.5)	24.5 (33.1)	8.6 (19.8)	8.1 (18.3)
After	34.3 (36.6)	35.3 (41.0)	25.9 (38.5)	33.8 (40.9)
Change	21.0 (37.1) <sup>b</sup>	10.8 (39.1)	17.3 (33.8) <sup>a</sup>	25.7 (44.2) <sup>b</sup>
Role emotional				
Before	50.5 (43.8)	54.9 (42.6)	44.9 (43.2)	42.3 (44.2)
After	59.1 (41.1)	65.7 (43.8)	47.4 (48.2)	68.9 (39.7)
Change	8.6 (43.6)	10.8 (48.4)	2.6 (57.3)	26.6 (50.2) <sup>b</sup>
General health				
Before	52.9 (20.2)	53.7 (21.7)	50.1 (20.7)	48.1 (16.6)
After	59.6 (19.1)	58.2 (22.0)	53.8 (20.0)	61.1 (16.1)
Change	6.7 (18.0) <sup>c</sup>	4.5 (16.2)	3.7 (15.0)	13.0 (13.6) <sup>d</sup>

(continued)

tervention compared with that seen in the FSHC group (Table 2). Six-minute walk performances improved similarly among the 3 exercise groups (mean distance, 27-34 m;  $P=.006$ ) and were significantly different than performance in the FSHC group (mean distance, -26 m) (Table 3). Within-group improvements were maintained

on the FIQ (ST-FSHC and ST), SF-36 physical function (ST-FSHC, ST, and AE), and 6-minute walk (ST-FSHC and ST) at the 6-month follow-up. Follow-up analysis included the 77% of the cohort who completed the intervention and the 73% who completed all 3 time points. The data presented in **Figure 2** are from participants with data

**Table 2. Self-assessed Measures of Function, Symptom Severity, and Self-efficacy<sup>a</sup> (cont)**

Time Point	AE (n=35)	ST (n=35)	FSHC (n=27)	ST-FSHC (n=38)
Beck Depression Inventory				
Before	17.0 (10)	13.0 (9)	14.0 (10)	18.0 (10)
After	13.0 (10)	9.0 (8)	14.0 (12)	11.0 (9)
Change	-5.0 (7) <sup>d</sup>	-4.0 (7) <sup>b</sup>	-1.0 (5)	-7.0 (10) <sup>d,e</sup>
Self-efficacy scale, pain				
Before	60.6 (18.9)	61.7 (17.8)	67.8 (16.0)	61.7 (16.3)
After	70.4 (14.8)	64.2 (18.7)	56.9 (21.2)	69.3 (17.9)
Change	9.8 (20.1) <sup>b,e</sup>	2.5 (15.9) <sup>e</sup>	-11.0 (14.7) <sup>d</sup>	7.6 (18.7) <sup>c,e</sup>
Self-efficacy scale, other symptoms				
Before	60.5 (20.5)	64.5 (17.3)	65.9 (17.7)	61.9 (13.0)
After	68.7 (17.2)	71.4 (19.2)	59.6 (18.3)	70.8 (14.9)
Change	8.1 (20.3) <sup>c,e</sup>	6.8 (17.7) <sup>c,e</sup>	-6.3 (14.1) <sup>c</sup>	8.9 (14.1) <sup>d,e</sup>

Abbreviations: AE, aerobic and flexibility exercise; FIQ, Fibromyalgia Impact Questionnaire; FSHC, Fibromyalgia Self-Help Course; SF-36, 36-Item Short-Form Health Survey; ST, strength training, aerobic, and flexibility exercise; ST-FSHC, a combination of ST and FSHC.

<sup>a</sup>Data are presented as mean (SD).

<sup>b</sup> $P < .01$  for within-group changes.

<sup>c</sup> $P < .05$  for within-group changes.

<sup>d</sup> $P < .001$  for within-group changes.

<sup>e</sup>Between-group difference of change compared with the education group:  $P < .05$ .

**Table 3. Performance-Based Measures of Function<sup>a</sup>**

Time Point	AE (n=35)	ST (n=35)	FSHC (n=27)	ST-FSHC (n=38)
6-Minute walk distance, m				
Before	488 (79)	462 (80)	467 (86)	457 (76)
After	515 (68)	496 (74)	442 (123)	485 (73)
Change	27 (50) <sup>b,c</sup>	34 (37) <sup>c,d</sup>	-26 (70)	28 (50) <sup>b,c</sup>
Walking speed, km/h				
Before	1.36 (0.22)	1.29 (0.22)	1.3 (0.24)	1.27 (0.21)
After	1.43 (0.19)	1.38 (0.20)	1.29 (0.34)	1.35 (0.20)
Change	0.08 (0.14) <sup>b,c</sup>	0.09 (0.10) <sup>c,d</sup>	-0.11 (0.19)	0.08 (0.14) <sup>b,c</sup>
Heart rate, resting, min				
Before	77 (11)	76 (8)	76 (11)	75 (10)
After	76 (10)	77 (9)	76 (7)	75 (9)
Change	-1 (10)	1 (8)	0 (11)	0 (6)
Heart rate, immediately after walk, min				
Before	108 (16)	104 (11)	104 (17)	102 (16)
After	111 (18)	106 (15)	104 (13)	107 (17)
Change	3 (15)	2 (14)	0 (15)	5 (13) <sup>e</sup>
Chest press, lb				
Before	57 (20)	54 (17)	52 (14)	53 (18)
After	62 (18)	70 (16)	52 (20)	67 (18)
Change	5 (13) <sup>e</sup>	16 (15) <sup>c,d,f</sup>	0 (15)	14 (15) <sup>c,d,f</sup>
Leg press, lb				
Before	159 (70)	163 (69)	142 (64)	140 (59)
After	198 (82)	246 (97)	146 (77)	214 (77)
Change	39 (63) <sup>c,d</sup>	83 (69) <sup>c,d,f</sup>	4 (43)	74 (65) <sup>c,d,f</sup>

Abbreviations: AE, aerobic and flexibility exercise; FSHC, Fibromyalgia Self-Help Course; ST, strength training, aerobic, and flexibility exercise; ST-FSHC, a combination of ST and FSHC.

<sup>a</sup>Data are presented as mean (SD).

<sup>b</sup> $P < .01$  for within-group changes.

<sup>c</sup>Between-group difference of change compared with the education group:  $P < .05$ .

<sup>d</sup> $P < .001$  for within-group changes.

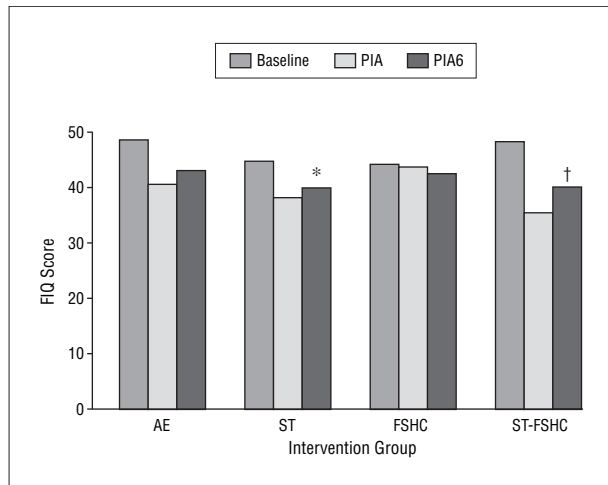
<sup>e</sup> $P < .05$  for within-group changes.

<sup>f</sup>Between-group difference of change compared with the exercise 1 group:  $P < .05$ .

at each of the 3 time points. The 6-month follow-up on this subset was similar to that on all participants evaluated at 6 months.

Secondary measures of function included additional domains of the SF-36 instrument (Table 2). The ST-FSHC group reported superior improvement in

social function scores compared with the FSHC group (mean difference, 21.8; 95% CI, 2.5 to 41.2), whereas the ST group showed within-group improvement. Additionally, improvements in mental health were seen in the ST-FSHC (mean±SD, 13.5±21.9;  $P < .001$ ) and ST (mean±SD, 7.5±12.0;  $P < .001$ ) groups.



**Figure 2.** Fibromyalgia Impact Questionnaire (FIQ) scores at baseline, postintervention assessment (PIA), and 6-month follow-up (PIA6) in the 4 intervention groups. A statistically significant improvement in score from baseline to 6-month follow-up is designated by the asterisk ( $P < .05$ ) and dagger ( $P < .001$ ). AE indicates aerobic and flexibility exercise; FSHC, Fibromyalgia Self-Help Course; ST, strength training, aerobic, and flexibility exercise; and ST-FSHC, a combination of ST and FSHC.

## SYMPTOMS AND SELF-EFFICACY

The ST-FSHC and AE groups reported within-group improvements in pain (26% and 20%, respectively) on the FIQ, and all 3 exercise groups improved on the bodily pain subscale (Table 2). Fatigue in the morning and throughout the day as measured on the FIQ improved in the exercise groups and remained relatively unchanged in the FSHC group. Corresponding changes in the vitality score of the SF-36 showed a sizeable improvement in the ST-FSHC (mean, 17.7;  $P < .001$ ) and AE (mean, 11.4;  $P = .006$ ) groups. Scores on the Beck Depression Inventory improved in the exercise groups; only the change in the ST-FSHC group (mean difference,  $-6.2$ ; 95% CI,  $-1.1$  to  $-11.3$ ) was greater than that seen in the FSHC group.

The ST-FSHC (mean difference, 18.5; 95% CI, 6.4 to 30.6) and AE (mean difference, 20.8; 95% CI, 8.5 to 33.0) groups showed improvements in perceived control over pain compared with the FSHC group (Table 2). Similarly, compared with the FSHC group, control over other symptoms of fibromyalgia was improved in the ST-FSHC (mean difference, 15.2; 95% CI, 3.6 to 26.9), AE (mean difference, 14.5; 95% CI, 2.6 to 26.3), and ST (mean difference, 13.2; 95% CI, 1.0 to 25.3) groups.

## COMMENT

Findings of this randomized trial suggest that an appropriately structured exercise program that involves progressive walking and flexibility movements with or without strength training improves physical, emotional, and social function, key symptoms, and self-efficacy in women with fibromyalgia being actively treated with medication. Moreover, when a comprehensive exercise program of strength training, walking, and flexibility is combined with group-based self-management education, the beneficial effects are enhanced. The comprehensive ex-

ercise program with or without additional education appears best for maintaining short-term improvements in physical function. The observed substantial benefit of exercise, an enhanced effect when combined with education and the maintenance of benefit 6 months after completion of the group intervention, suggests that an intervention that addresses physical, psychosocial, and behavioral factors may be the best approach to self-management in women with fibromyalgia.

Self-efficacy is a mediator of functional status and symptom severity that can be influenced by physical fitness and education.<sup>37,42</sup> We observed an improvement in self-efficacy in the exercise-only and combined groups and a worsening in the education-only group. We speculate that exercise may improve self-efficacy by demonstrating the capacity to complete certain physical tasks through regularly performing particular exercise activities.<sup>43</sup> This positive experience may reduce the fear of pain and movement common in this patient population.<sup>44</sup> The decline in self-efficacy scores observed in the FSHC group was unexpected<sup>20,21,45,46</sup> and may have been a result of the desire of participants to be in an exercise group.

A growing body of literature suggests that exercise and education interventions alone and in combination are beneficial for people with fibromyalgia; however, the content and duration of interventions and outcomes vary greatly.<sup>20-22,24,27,40,47-51</sup> Our findings extend the knowledge base of fibromyalgia self-management by demonstrating numerous benefits of 2 easily prescribed exercise programs and clarify enhanced effects when combined with targeted education. We did not observe the magnitude of change in the education and combination groups as hypothesized. We believe that this was due to the apparent ineffectiveness of the education intervention in this study. With the many acknowledged health benefits of walking, strength training, and flexibility exercise,<sup>52</sup> we believe that these data provide sufficient evidence to encourage health care professionals to recommend a program of progressive walking and flexibility with or without moderate strength training to their patients with fibromyalgia.

Our study has several limitations and strengths. We chose not to have a group that received no intervention to minimize the bias of interpersonal contact received by participants in active interventions. Therefore, we cannot determine how an intervention group compares with no treatment. Approximately one-third of the overall sample dropped out, which was similar to previous studies<sup>19</sup> in fibromyalgia populations that used comparable exercise interventions. Strengths include the randomized design, recruitment approach, minimal exclusion criteria, and use of standard self-report and objective measures and masked test administrators. The exercise and education interventions were administered within a preplanned format that promoted improvement without exacerbating symptoms, used a national education program with instructor training, and had good adherence.

The findings of this study contribute to the growing body of knowledge on the benefits of exercise and physical activity for improving the health and function of adults with chronic illness.<sup>53</sup> People with rheumatic condi-

tions are even less active than the relatively sedentary general public.<sup>54</sup> Future studies are needed to identify ways of integrating appropriate exercise into the treatment plans of people with fibromyalgia and other chronic illnesses and to promote the adoption and maintenance of a more physically active lifestyle. Mechanisms of improvement brought about by exercise and education should also be examined.

The present study suggests that progressive walking, simple strength training movements, and stretching activities are effective at improving physical, emotional, and social function, key symptoms, and self-efficacy in women with fibromyalgia who are being actively treated with medication. Furthermore, the benefits of exercise are enhanced when combined with targeted self-management education, and improvements in physical function continue for 6 months after completion of the intervention. Our findings suggest the need for inclusion of appropriate exercise and patient education in the treatment of individuals with fibromyalgia.

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