ORIGINAL ARTICLE

Aerobic Exercise Versus Combined Exercise Therapy in Women With Fibromyalgia Syndrome: A Randomized Controlled Trial

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ABSTRACT. Sañudo B, Galiano D, Carrasco L, Blagojevic M, de Hoyo M, Saxton J. Aerobic exercise versus combined exercise therapy in women with fibromyalgia syndrome: a randomized controlled trial. Arch Phys Med Rehabil 2010;91: 1838-43.

Objective: To investigate the effects of supervised aerobic exercise (AE) and a combined program of supervised aerobic, muscle strengthening, and flexibility exercises (combined exercise [CE]) on important health outcomes in women with fibromyalgia syndrome (FMS).

Design: Randomized controlled trial.

Setting: Community-based supervised intervention.

Participants: Women (N=64) with a diagnosis of FMS according to the American College of Rheumatology criteria.

Intervention: Participants were randomly allocated to 1 of 3 groups: supervised AE, supervised CE, or usual-care control. Exercise sessions were performed twice weekly (45–60min/session) for 24 weeks.

Main Outcome Measures: The primary outcome measure was the Fibromyalgia Impact Questionnaire (FIQ). Exploratory outcome measures were the 36-Item Short-Form Health Survey, Beck Depression Inventory (BDI), aerobic capacity (6-minute walk test), hand-grip strength, and range of motion in the shoulders and hips.

Results: Compliance with both interventions was excellent, with women in the exercise groups attending more than 85% of sessions. A 14% to 15% improvement from baseline in total FIQ score was observed in the exercise groups ($P \leq .02$) and was accompanied by decreases in BDI scores of 8.5 ($P < .001$) and 6.4 ($P < .001$) points in the AE and CE groups, respectively. Relative to nonexercising controls, CE evoked improvements in the SF-36 Physical Functioning ($P = .003$) and Bodily Pain ($P = .003$) domains and was more effective than AE for evoking improvements in the Vitality ($P = .002$) and Mental Health ($P = .04$) domains. Greater improvements also were observed in shoulder/hip range of motion and handgrip strength in the CE group.

Conclusion: Given the equivalent time commitment required for AE and CE, our results suggest that women with FMS can gain additional health benefits by engaging in a similar volume of CE.

Key Words: Aerobic exercise; Combination exercise; Fibromyalgia; Rehabilitation.

FIBROMYALGIA SYNDROME is a common chronic pain condition in which patients often show a range of other symptoms, including sleep disturbance, fatigue, stiffness, and alterations in psychological health status.[1] Although several treatment options are available, optimal management of FMS is unknown. Clinical guidance (based on current scientific evidence) recommends a broad range of pharmacologic and nonpharmacologic therapies. However, such treatments cannot reliably resolve functional limitations and the deterioration in quality of life.[2,3]

Physical exercise is considered to be the main nonpharmacologic treatment in the management of FMS, but many clinically relevant and practically important questions remain.[4,5] In particular, the most effective method of implementing supervised exercise therapy in this patient group is unknown. Recent systematic reviews[4-7] have reported "moderate quality evidence" to show that short-term programs of supervised AE produce important health benefits in people with FMS in terms of global outcome measures, physical function, and pain. However, because patients with FMS frequently report symptoms of widespread joint stiffness and muscle fatigue, the addition of muscle strengthening and flexibility exercises to a structured program of AE might augment the impact of the latter on FMS-specific symptoms. Recently, Valkeinen et al[8] concluded that concurrent strength and AE training in low to moderate volume improved functional capacity and symptom severity in patients with FMS, although the investigators emphasized the need for more extensive studies to confirm these results.

The aim of this study was to investigate the effects of supervised AE and a combined program of supervised combined aerobic, muscle strengthening, and flexibility exercises

List of Abbreviations

AE	aerobic exercise
BDI	Beck Depression Inventory
CE	combined exercise
FIQ	Fibromyalgia Impact Questionnaire
FMS	Fibromyalgia syndrome
HR_{max}	predicted maximum heart rate
SF-36	Medical Outcomes Study 36-Item Short Form Health Survey

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(CE) on important health outcomes in women with a diagnosis of FMS. It was hypothesized that a combined program of exercise training (of similar volume) would evoke improvements in a greater range of health outcomes than a program of AE therapy alone.

METHODS

Participants and Randomization

Women (N=64) who met the American College of Rheumatology criteria for classification of fibromyalgia[1] were recruited to the study from physician practices and local FMS support groups in Seville, Spain. Participants were randomly assigned by using a computer-generated random number sequence to either an AE group (n=22), CE group (n=21), or usual-care control group (n=21). Randomization was undertaken by a member of the research team not directly involved in the recruitment or assessment of patients, and the randomization list was kept at a separate location in a locked filing cabinet. The randomization sequence was not disclosed to the researcher responsible for the day-to-day running of the trial (B.S.) until patients had completed their baseline assessments. Exclusion criteria included the presence of inflammatory rheumatic diseases and severe psychiatric illness. Participants with respiratory or cardiovascular diseases that prevent physical exertion also were omitted. Finally, women with FMS receiving psychological or physical therapy were excluded to avoid possible interactions with the present trial. Patients were screened for entry into the study from March 2006 to December 2006. Follow-up assessments were completed for all patients by December 2007. Demographic variables for the 3 groups, including age, anthropometric, physical fitness, and questionnaire data, are listed in table 1. This research was carried out according to the Declaration of Helsinki of the World Medical Association and was approved by the University of Seville Research Ethics Committee.

Sample-Size Calculation

The primary outcome measure for this study was change in FIQ score at the 24-week point. Gowans et al[9] reported a mean ± SD improvement of 9.6±14 points in FIQ score after a 6-month AE intervention in patients with FMS, representing an 18% change from baseline (a 14% change in FIQ score is regarded as clinically important[10]). This 18% change was accompanied by improvements in depression and physical functioning. On this basis, sample-size calculations indicated that 54 participants (18 in each group) were needed to show an improvement in FIQ score of this magnitude, using a power of 0.8 and α level of .05. Allowing 15% loss to follow-up, the recruitment target was 21 participants for each group.

Outcome Measures

Assessment of outcomes was undertaken at baseline and immediately after the 24-week intervention and at the same times in the usual-care control group. Outcome measures were assessed blindly by a member of the research team who was unaware of group assignment and was not directly involved in the day-to-day running of the study (D.G.).

Primary outcome measure. The primary outcome of the study was change in FIQ score from baseline to completion of the 24-week intervention. The FIQ is a disease-specific measure of global health status that has been validated for Spanish populations with FMS.[11] Total scores range from 0 to 100, with higher scores indicating more severe symptoms and disability.

Secondary outcome measures. The SF-36, a widely used generic health-related quality-of-life instrument, also has been validated in Spanish populations[12] and was used to assess 8 health concepts: Physical Functioning, Role–Physical, Bodily Pain, Vitality, Role–Emotional, Social Functioning, Mental Health, and General Health. Scores for each dimension range from 0 (poor health) to 100 (good health).

Depression was assessed using the BDI.[13] This is a 21-item inventory (range, 0–63), with higher score indicating greater depression, that is recommended for assessment of change in depression after exercise interventions in patients with a diagnosis of FMS.[5] The 6-minute walk test was used to estimate aerobic capacity and is a reliable and valid measure in patients with fibromyalgia.[14] Hand-grip strength was assessed in both hands by using a hand dynamometer,[a] following the American College of Sports Medicine recommendations.[15] Range of motion (flexion/extension) in the shoulders and hips was assessed by using a manual goniometer,[b] with the best of 3 trials recorded.

Supervised Exercise Interventions

Participants randomly assigned to AE performed 2 AE sessions a week of 45 to 60 minutes' duration. Each session included 10 minutes of warm-up activities (slow walks, easy

Table 1: Baseline Values for the 3 Groups

Variable	AE	CE	Control Group	*P*
Age (y)	55.9±1.6 (44–70)	55.9±1.7 (47–72)	56.6±1.9 (36–74)	.953
Body mass index (kg/m^2)	29.6±1.1 (21.4–40.4)	27.6±1.1 (22.5–36.1)	29.7±1.1 (22.9–39.8)	.304
Body weight (kg)	72.3±2.3 (53.0–85.9)	68.5±3.0 (55.0–94.9)	74.5±3.3 (53.0–115)	.359
Height (m)	1.57±0.01 (1.45–1.66)	1.57±0.02 (1.45–1.74)	1.58±0.01 (1.43–1.70)	.848
Right hip ROM (°)	66±3 (50–85)	72±3 (52–90)	68±3 (45–89)	.324
Left hip ROM (°)	65±3 (45–82)	69±2 (59–87)	71±3 (48–96)	.213
Right shoulder ROM (°)	149±3 (115–170)	144±6 (79–180)	142±3 (123–165)	.518
Left shoulder ROM (°)	146±3 (120–175)	153±4 (109–187)	146±3 (125–165)	.278
6-Min walk test (s)	512.5±15.9 (407.5–616.3)	535.0±16.2 (395.8–631.9)	488.7±16.9 (315.0–600.0)	.146
Right hand grip strength (N)	17.6±1.2 (5.0–23.3)	17.3±1.2 (8.6–27.0)	17.9±1.1 (9.9–25.6)	.928
Left hand grip strength (N)	16.2±0.9 (10.0–23.3)	16.0±0.9 (10.3–24.7)	16.9±1.4 (8.7–32.1)	.824
FIQ score	60.9±3.4 (28.4–81.6)	62.2±4.2 (27.9–90.0)	60.5±3.8 (27.4–88.0)	.947
BDI score	28±4 (2–45)	25±3 (0–45)	31±3 (5–45)	.425
SF-36 score	36.1±2.9 (12.1–53.4)	39.1±3.9 (7.4–61.4)	37.7±3.3 (14.8–61.0)	.834

NOTE. Data reported as mean ± SE (range).
Abbreviation: ROM, range of motion.

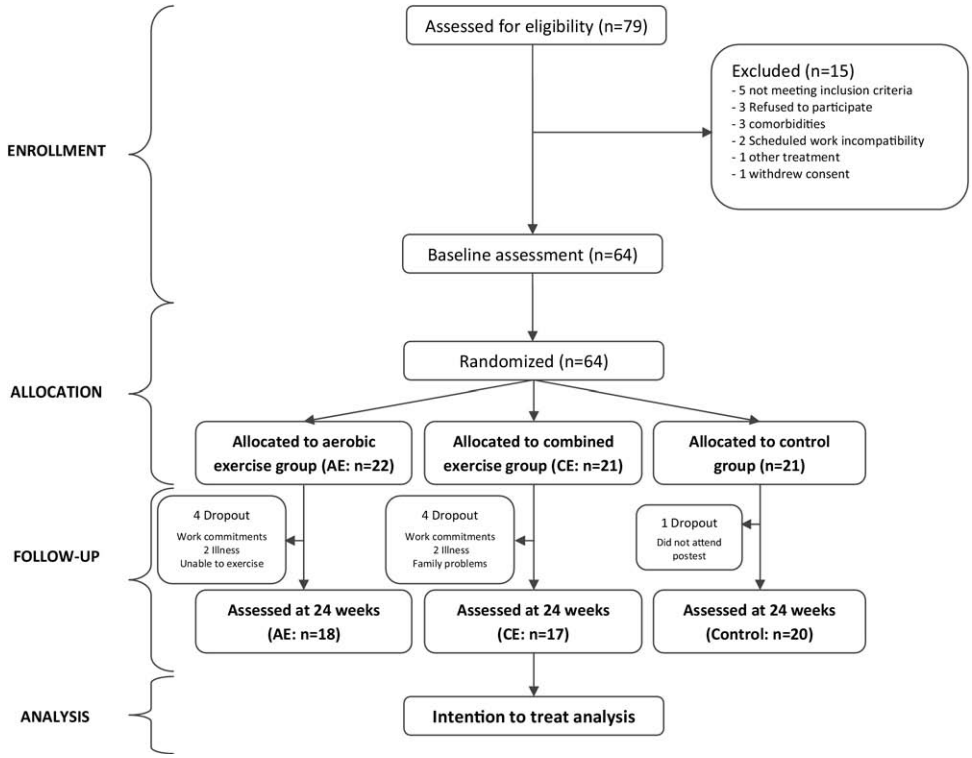

Fig 1. Enrollment, randomization, and retention of study sample.

movements of progressive intensity); 15 to 20 minutes of steady-state AE at 60% to 65% of HR_{max} (calculated as 220 − age of participant), including continuous walking with arm movements and jogging; 15 minutes of interval training at 75% to 80% HR_{max} (6 exercises for 1.5 minute, resting for 1 minute between them) that included aerobic dance and jogging; and 5 to 10 minutes of cool-down activities (slow walks, easy movements, relaxation training). Participants randomly assigned to CE performed twice-weekly sessions of combined AE and resistance exercise with the same duration, including a 10-minute warm up, 10 to 15 minutes of AE at 65% to 70% HR_{max}, 15 to 20 minutes of muscle strengthening exercises (1 set of 8–10 repetitions for 8 different muscle groups, with a load of 1–3kg), and 10 minutes of flexibility exercises (1 set of 3 repetitions for 8–9 different exercises, maintaining the stretched position for 30 seconds). Strengthening and flexibility exercises focused on the main areas of pain in patients with FMS (deltoids, biceps, neck [trapezius], hip [gluteus, quádriceps], back/chest/torso [latissimus dorsi, pectoralis major, abdominals]). The usual-care control group was receiving medical treatment for FMS and continued their normal daily activities during the intervention period, which did not include structured exercise. Heart rate was used to measure the intensity of exercise and was determined by using a telemetric system.[c] This enabled participants to exercise within their established intensity thresholds.

Statistical Analyses

Intention-to-treat analysis was used to compare participants in the groups to which they were randomly assigned, with data carried over from previous visits in cases of patient withdrawal. Changes in dependent variables over time within groups and differences between groups at the same times were evaluated using repeated-measures analysis of variance with corresponding post hoc Bonferroni-corrected *t* tests. Data distributions were relatively asymmetrical for some variables; hence, bootstrapping with 1000 replicates was performed. Results based on the normality assumption were found to be reliable. Data were analyzed blindly using Stata[d] by a statistician who was not involved in the day-to-day running of the trial. Statistical significance was assumed at P less than .05.

RESULTS

Four women from each exercise group and 1 woman from the usual-care control group were lost to follow-up (fig 1). Reasons for dropout included illness, unforeseen work commitments, unable to exercise after an injury, and serious family problems (1 participant). Additionally, 1 patient did not attend the final evaluation session. Hence, follow-up data were available for 18 of 22 women in the AE group, 17 of 21 women in the CE group, and 20 of 21 women in the control group. Compliance with the exercise interventions was excellent, with women in the AE group attending an average of 43 of 48 (89%) sessions and women in the CE group attending 41 of 48 (86%) sessions. Table 1 lists baseline characteristics of the 3 groups. The groups were well matched at the baseline assessment, with no differences in key outcome variables apparent.

An improvement of approximately 9 points (14%–15%) from baseline FIQ score was observed in both exercising groups at 24 weeks (AE, 8.8±14; CE, 8.8±12; $P \leq .020$). Improvements in depression scores and health-related quality of life from baseline values also were observed in both exercising groups. BDI scores decreased by 8.5±8 ($P < .001$) and 6.4±4 points ($P < .001$) in the AE and CE groups, respectively. Improvement in global SF-36 scores in excess of 8 points was observed in the exercising groups (AE, 8.9±10; CE, 8.4±11;

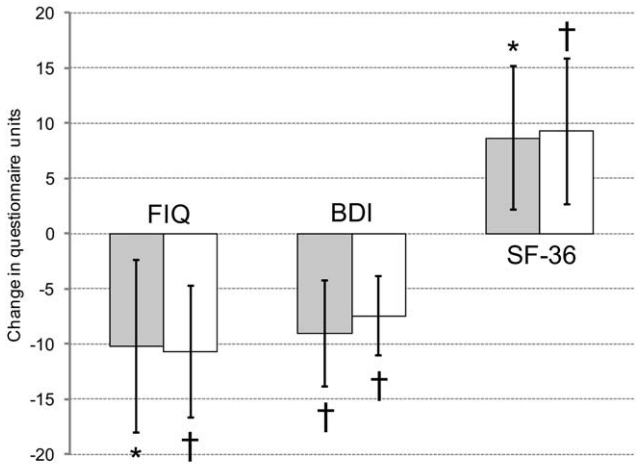

Fig 2. Relative changes in FIQ, BDI, and global SF-36 scores among the exercise groups and controls at 24 weeks. Grey (AE) and white (CE) columns indicate geometric mean differences between the exercise groups and controls, with error bars representing 95% confidence intervals. *$P<.05$; †$P<.01$ between the exercise and control groups.

$P<.01$). Regarding the latter, improvements were significant for the Physical Functioning ($P=.002$) and Social Functioning ($P=.017$) dimensions in AE participants, whereas for CE participants, significant improvements were observed for the Physical Functioning ($P=.027$), Bodily Pain ($P=.041$), Vitality ($P=.009$), and Mental Health dimensions ($P=.035$). There was no change from baseline values in FIQ, BDI, or global SF-36 scores in controls.

The improvements in FIQ, depression, and global SF-36 scores observed in the exercising groups were of a magnitude similar to controls. Figure 2 shows relative changes in FIQ, BDI, and global SF-36 scores among exercising groups and controls at 24 weeks. In contrast, changes in joint mobility and strength variables were more pronounced in relation to controls in participants randomly assigned to CE. In this group, joint mobility in both shoulders ($P\leq.014$) and the right hip ($P<.001$) were significantly greater than for controls at 24 weeks, and there was a strong trend for greater mobility in the left hip ($P=.06$). However, the AE group showed greater mobility than controls in only the left shoulder at the postintervention assessment (fig 3). Furthermore, both left and right grip strength were higher in the CE group than controls at 24 weeks ($P\leq.012$), whereas there was no difference in grip strength between the AE and control group. Effect-size differences for these variables and for individual SF-36 domains between the exercising groups and controls (expressed in SD units) are shown in figure 4. Generally, greater effect-size differences were observed for the CE group. Although not significant from baseline values, similar trends for a 4% to 5% improvement in 6-minute walk time were observed in both the AE ($P=.088$) and CE ($P=.078$) groups.

DISCUSSION

The AE and CE interventions evoked improvements in FMS-specific symptoms (evidenced by changes in FIQ scores), depression, and global SF-36 scores. The magnitude of improvement in FIQ scores (14%–15% in both exercising groups) constitutes a clinically relevant change in patients with FMS[10] and is similar to those reported previously after AE interventions in some studies,[16-18] although greater changes have been observed in others.[19,20] The more pronounced changes in FIQ score observed in the latter studies likely are due to differences in characteristics of the participants or exercise programs, for example, frequency, intensity, duration, modality, and total volume of exercise. In the present study, participants in the AE and CE groups exercised at an intensity of 60% to 80% of HR_{max}, which has been recommended for optimizing cardiovascular adaptations in previously sedentary people,[21] and there is evidence that greater changes in total FIQ score can be evoked by exercise of this intensity in comparison to gentle aerobic exercise.[19,20] Interestingly, in our patient cohort, similar nonsignificant trends for improvement in 6-minute walking distance were observed in both exercise groups despite a decreased total volume of AE for participants in the CE group.

Few studies have investigated the impact of chronic resistance (strength) or flexibility exercise in isolation on FMS-specific symptoms, assessed using the FIQ. However, 1 study reported no change in mean FIQ score after 12 weeks of strength-training exercises,[22] whereas a second study reported a 21% improvement in average FIQ score after a 12-week program of strength-training exercises, but no change after a flexibility exercise regimen.[23] Other evidence suggests that programs of supervised strength or AE have a greater impact on FIQ scores than flexibility training.[17,23,24] Interestingly, our results suggest that the improvement in FIQ score that can be evoked by 24 weeks of AE is neither enhanced nor diminished by replacing some of the AE time with resistance and flexibility exercises.

The improvement in average BDI score in the AE group was similar to that previously reported after AE interventions.[16,17,20] There also is limited evidence that strength training can improve depressive symptoms in patients with FMS,[23,24] although these studies suggested that the changes in BDI scores evoked by strength training are less pronounced. Furthermore, 2 studies that investigated the impact of flexibility training on BDI scores in patients with FMS reported no change in this outcome.[17,23] In the present study, the decrease in average BDI score was greater in the AE group in comparison to the CE group (8.5 vs 6.4 units), although this difference

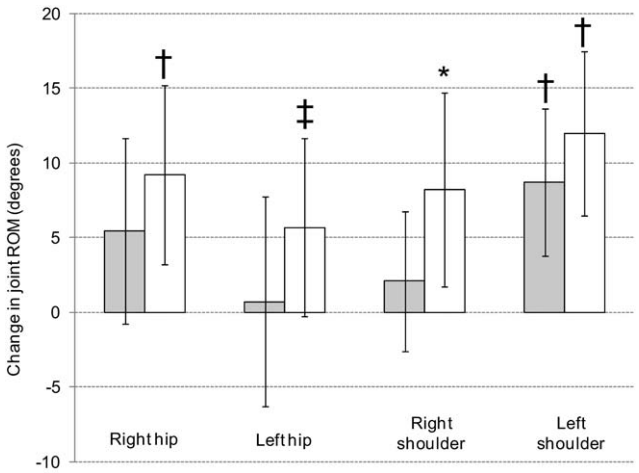

Fig 3. Relative changes in joint mobility between the exercise groups and controls at 24 weeks. Grey (AE) and white (CE) columns indicate geometric mean differences between the exercise groups and controls, with error bars representing 95% confidence intervals. *$P<.05$; †$P<.01$; ‡$P=.06$ between the exercise and control groups. Abbreviation: ROM, range of motion.

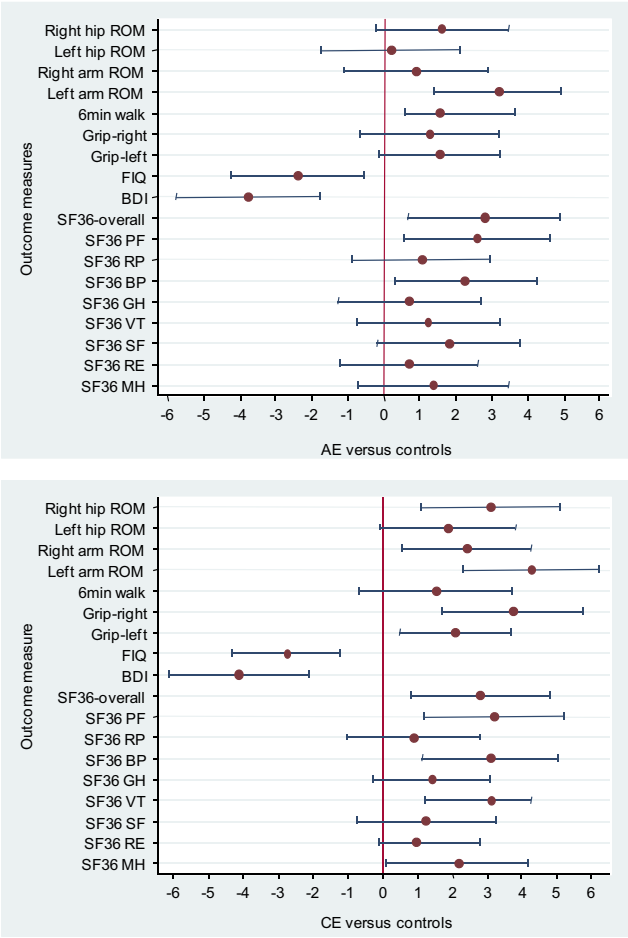

Fig 4. Effect-size differences (with 95% confidence intervals) for fitness variables, depression, and individual health status (SF-36 domains and FIQ) between the exercise groups and controls (expressed in SD units). Abbreviations: BP, Bodily Pain; GH, General Health; MH, Mental Health; PF, Physical Functioning; RE, Role–Emotional; ROM, range of motion; RP, Role–Physical; SF, Social Functioning; VT, vitality.

was not statistically significant because of a lack of statistical power. Nevertheless, this result, considered in the context of those previously reported for long-term strength and flexibility training, suggests that replacing some of the AE time with strength and flexibility exercises might decrease the impact of AE on symptoms of depression.

Although changes in global SF-36 scores were similar across exercising groups, improvements in a broader range of individual SF-36 domains were observed after the CE intervention. Furthermore, effect-size changes in relation to controls generally were greater than those observed after the program of AE (see fig 3). Participants in the CE group experienced improvements in Physical Functioning, Mental Health, Bodily Pain, and Vitality in relation to the nonexercising control participants, indicative of enhanced physical and psychological well-being, decreased pain levels, and increased perception of energy. For participants in the AE group, improvements relative to nonexercising controls were limited to the Physical Functioning and Bodily Pain domains of the SF-36.

Improvements in both physical and mental health SF-36 quality-of-life domains have been reported previously after AE[17,20,25] and strength-training[24] interventions, whereas programs that consist of only flexibility exercises have yielded conflicting results for quality of life.[17,23] The more pronounced improvements in SF-36 domain scores that we observed in participants who were allocated to CE might have been influenced by the greater improvements in hip and shoulder joint mobility and increase in grip strength (vs controls), which was not observed in the AE group. Accordingly, the enhancement of joint mobility observed in this group might have had a significantly greater impact on the execution of normal daily activities, hence reflecting positively in a broader range of health-related quality-of-life domains. Similarly, the improvement in grip strength, which is likely to reflect wider improvements in upper-body strength, could have important consequences for the performance of everyday tasks because it is associated with functional independence in elderly populations.[26]

Study Limitations

A limitation of the present study was the lack of long-term follow-up measures beyond 24 weeks. Although adherence to both supervised exercise programs was very good, a decrease in exercise adherence is common when supervised exercise programs have ended. Hence, the present study does not provide insight into the impact of 24-week supervised programs of AE and CE on longer term changes in exercise behavior. Another limitation of this study was the limited range of outcome measures assessed, although consideration has to be given to patient burden when designing assessment protocols. The impact of the exercise programs on key factors affecting quality of life, such as disturbed sleep patterns (a common problem in patients with FMS) and medication use, is unknown. Focus groups and structured interviews are effective ways to glean such additional information and should be built in to trial designs when possible.

CONCLUSIONS

Given the equivalent time commitment required for the AE and CE interventions, our results suggest that women with a diagnosis of FMS can gain additional health benefits by engaging in combined supervised strength, flexibility, and aerobic exercise. Improvements in FMS-specific symptoms were not compromised by replacing some of the AE time with resistance and flexibility exercises, and more pronounced changes in joint mobility, upper-body (grip) strength, and SF-36 domains were observed in the CE group. Although it presently is unclear whether equivalent volumes of exclusively AE have a greater impact on depressive symptoms, results of this study support a rationale for including strength and flexibility exercises in programs of AE rehabilitation for women with FMS.

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