Utilizing exercise to affect the symptomology of fibromyalgia: a pilot study

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ABSTRACT

MEYER, B. B., and K. J. LEMLEY. Utilizing exercise to affect the symptomology of fibromyalgia: a pilot study. *Med. Sci. Sports Exerc.*, Vol. 32, No. 10, pp. 1691–1697, 2000. Fibromyalgia (FM), a rheumatological disorder of unknown origin, is characterized by both physical and psychological symptoms. Although inconclusive results have been reported for most treatment modalities, exercise appears to have universal support for decreasing the myriad of symptoms associated with FM. Weaknesses in the literature, however, prevent conclusive statements regarding exercise prescription and concomitant impact on FM symptomology. **Purpose:** The current pilot study attempted to examine the effect of a 24-wk walking program at predetermined intensities on FM. **Methods:** Initial design was a randomized control trial with high- and low-intensity exercise groups, and a control group. Subsequent nonrandomized control trials were based on actual exercise behavior. **Results:** No differences between initial groups were identified. By collapsing groups, heart rate (HR) decreased ($P < 0.05$) weeks 0–12. Functional impairments were reduced 54% weeks 0–24, with exercise having a large impact ($\omega^2 = 0.30$) on this decrease. By reassigning groups, impact of FM on current health status decreased in the low-intensity group ($P < 0.05$) and increased in the high-intensity group ($P < 0.02$) weeks 0–24. Omega squared indicated strong influence of exercise on pain ($\omega^2 = 0.51$), with greater pain in the high-intensity group. **Conclusions:** A larger number of subjects and direct supervision of the training program to increase compliance is necessary to clarify the effects of a walking program on the manifestations of FM. Results indicate that intensity of the walking program is an important consideration. Individuals with FM can adhere to low-intensity walking programs two to three times per week, possibly reducing FM impact on daily activities. **Key Words:** FIBROMYALGIA, RHEUMATOLOGY, EXERCISE PRESCRIPTION, PHYSICAL ACTIVITY, WALKING

There are approximately 6 million individuals in the United States diagnosed with fibromyalgia (FM), making it the third most prevalent rheumatological disorder in this country (4). Eighty percent of those afflicted are women, usually between the ages of 20 and 55 yr (8). FM is a complex condition characterized by the presence of chronic diffuse pain and tenderness upon the application of moderate pressure at specific anatomic locations (4,7,8,15,37). Additional clinical signs often found in association with FM include sleep disturbance, chronic fatigue, morning stiffness, paresthesias in the extremities, irritable bowel syndrome, anxiety, and depression (4,7,15).

Inability to identify a specific causal mechanism for FM has resulted in a shift in the focus of research from etiology to treatment. Although research into pharmacological and cognitive behavioral interventions have yielded few if any long-term conclusive results (3,10,18,23,26), investigations into the effect of aerobic exercise on the physiological and psychological symptoms of FM have been more favorable. Reported physical benefits of aerobic exercise include decreased feelings of muscle tension (22), reduced physical dysfunction (10), a reduction in the number of tender points (TP) (18), a reduction in tenderness at TP (10,18), and a trend toward decreased pain (18,21,27). Psychological benefits include increased feelings of well-being (22), decreased feelings of helplessness, and increased self-efficacy (10), as well as decreased depression and anxiety (7).

Although it is apparent that aerobic exercise is beneficial for individuals with FM, the absence of a definitive effect of exercise on pain is disconcerting. Specifically, research implies that there is an exacerbation of symptoms upon initiating an aerobic exercise program that gradually reverses itself as regular aerobic exercise is continued (18,21,22). Thus, investigations lasting 20 wk or less may be of insufficient duration to detect an improvement in pain intensity. Additional methodological issues have made it difficult to appropriately prescribe aerobic exercise for individuals with FM. Multiple modes of exercise have been utilized, including cycling (21), modified low-impact aerobic dance (22), and walking (27). Still others have used a variety of modes within the same subject group (10,18).

Different levels of exercise intensity and inconsistent methods of determining exercise intensity (e.g., arbitrary heart rate vs percent heart rate reserve [% HRR]), have also

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TABLE 1. Subject demographic and select clinical variables upon entry to the study.

Variable	Mean	SD	Range	No. of Subjects
Gender—female/male				8/0
Age	49.5	6.3	39–57	8
Years in pain	13.1	15.5	2–40	8
No. of TP	11.9	1.7	11–16	8

limited the possible assimilation of aerobic exercise into clinical practice. Although most researchers have used low to moderate levels of exercise (18,22,27), others have failed to specify the intensity utilized (10). Only one study has examined the effects of moderate to high-intensity exercise on the symptoms of FM (21). Although the findings of the aforementioned study are provocative, the abbreviated treatment length and the use of cycling, a mode of exercise that may be difficult for individuals with gluteal tender points (11), limit application of the results.

Overall, previous research into the effect of aerobic exercise on FM has been limited by several factors, including the absence of longitudinal studies, the use of a wide spectrum of exercise intensities, and the use of multiple modes of exercise. A comparison of the effects of a single mode of aerobic exercise, at various yet fixed intensities, upon the symptoms of FM is necessary in order to establish a reliable data base on the responses of this patient population to exercise.

The overall purpose of this pilot study was to examine the effects of a 24-wk walking program at high and low intensity on the physical and psychological manifestations of FM. In addressing this issue the authors attempted to: (a) determine the duration of exercise training required to observe improvements in the physical and psychological symptoms of FM, (b) examine the ability of individuals with FM to maintain a training program of sufficient intensity to establish an aerobic training effect, and (c) address methodological issues for continued research in this area.

METHODS

Subjects

Inclusion in the study was based solely on meeting of the American College of Rheumatology (ACR) criteria for FM (37). The criteria for classification of FM are (a) widespread pain of at least 3 months' duration in combination with (b) tenderness at 11 or more of the 18 specific TP sites. Individuals were recruited by flyers mailed to various clinics, physician offices, and support groups. Individuals were excluded from the study if they reported: (a) experiencing pain for less than 3 months, (b) absence of widespread pain, (c) uncontrolled hypertension, (d) history of heart or respiratory disease, or (e) orthopedic dysfunction that would prevent them from regularly participating in a walking program. A summary of subject demographic and clinical variables upon entry to the study are presented in Table 1.

Design

Twenty-one individuals satisfied study criteria and, after providing written informed consent, were randomly assigned to either a high-intensity exercise group ($N = 8$), a low-intensity exercise group ($N = 8$), or a control group ($N = 5$). Study protocol included a 24-wk walking program of increasing intensity for those subjects in the high- and low-intensity groups, and instructions to maintain initial activity levels for those in the control group. All subjects underwent on-site physical and psychological testing at weeks 0, 12, and 24, as well as completion of weekly logs documenting physical activity, rating of perceived exertion (RPE), and FM impact on current health status.

Instruments

The responses of the subjects to aerobic exercise and the symptoms associated with FM were tracked utilizing psychological, physical, psychophysiological, and functional measures. A description of these measures appears below.

Tender point (TP). Tender points were measured using palpation by a single examiner in accordance with the ACR criteria for the classification of FM (37). Twelve control points (six pair) were also palpated in an attempt to detect false positives (7). No subject responded affirmatively to more than three control points, thus reducing the likelihood of malingering or somatization.

Resting heart rate (RHR). RHR was measured in beats per minute (bpm) by palpation of the radial pulse at the initial data collection period and by a Polar Edge (Port Washington, NY) heart rate monitor at subsequent sessions. RHR was taken after 10 min of quiet sitting.

Heart rate (HR). HR was measured in bpm during treadmill testing by a Polar Edge heart rate monitor. Subjects were instructed during their week 0 appointment to measure heart rate by palpation of the radial and/or carotid pulse during unsupervised bouts of physical activity.

Blood lactate. Blood lactate (mmol) levels were measured using 50-ìL blood samples taken via finger stick technique. Lactate levels were analyzed utilizing the YSI Sport 1500 Lactate Analyzer (Yellow Springs, OH). A single examiner performed all finger sticks and lactate analyses at each of the three data collection periods.

Rating of perceived exertion (RPE). The 10-point Borg RPE scale was utilized to measure individual levels of perceived exertion during treadmill testing and unsupervised bouts of exercise at home.

Fibromyalgia Impact Questionnaire (FIQ). Current health status (i.e., physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and feelings of well-being) was assessed via the 10-item, self-administered FIQ. A higher score on the FIQ indicates a greater impact of FM on the individual. The FIQ is shown to have adequate reliability and validity (9). Internal consistency reliability (i.e., consistency of the assessment inventory across all of its component parts) for the FIQ in the current study was established through calculation of a Cronbach's alpha coefficient and is reported at 0.71. Given that the accepted

standard for internal reliability is 0.70 (29), the FIQ demonstrates adequate levels of internal consistency.

Beck Depression Inventory (BDI). Depression was assessed via the 21-item, self-administered BDI. Scores on the BDI range from 0 to 63, with higher scores indicating more severe levels of depression. In normal populations, a score over 16 indicates possible depression. The BDI has high reliability and validity in nonclinical populations (5). Internal consistency reliability for the BDI in the current study was established through calculation of a Cronbach's alpha coefficient and is reported at 0.88.

State Anxiety Inventory (SAI). Level of current anxiety (e.g., apprehension, tension, nervousness, and worry) was measured with the 20-item, self-administered SAI. Higher scores on the SAI indicate greater state anxiety. Median internal consistency of the SAI is reported at 0.92, with validity ranging from 0.86 to 0.92 (34). Internal consistency reliability for the SAI in the current study was established through calculation of a Cronbach's alpha coefficient and is reported at 0.84.

Pain. The pain scale of the Health Assessment Questionnaire (HAQ) was used to measure the intensity of FM-related pain (30). A score from 0 (no pain) to 3 (severe pain) was recorded based upon the location of the subject's mark on a 15-cm line. Internal consistency reliability for the pain score in the current study was established through calculation of a Cronbach's alpha coefficient and is reported at 0.74.

Health Assessment Questionnaire Disability Index (HAQ-SDI). The HAQ-SDI is a self-report measure designed to assess a subject's functional ability over the past week. In addition to assessing ability to undertake eight activities of daily living (ADLs), the HAQ-SDI assesses the use of an aid or physical assistance in each activity. Scores range from 0 to 3, with a higher score indicating greater difficulty and more assistance. The HAQ-SDI has been shown to have adequate reliability, as well as face, content, and convergent validity (30). Internal consistency reliability for the HAQ-SDI in the current study was established through calculation of a Cronbach's alpha coefficient and is reported at 0.78.

Procedures

Upon arriving at the testing site, subjects were taken to a quiet room to complete the FIQ, BDI, HAQ pain index, HAQ-SDI, and SAI. Tender point measures were then taken. Subjects were instructed in the monitoring of heart rate by palpation of the radial and/or carotid pulse.

To assess the physiological response to submaximal aerobic exercise, subjects performed a submaximal treadmill test in accordance with the Modified Balke Protocol (2) during each of the three on-site testing sessions. At the end of each 3-min stage, HR and RPE were assessed, and a capillary blood sample for lactate testing was collected via fingerstick technique. The treadmill test continued until the subject expressed a desire to stop or the researchers noted poor tolerance for the activity. Duration of the treadmill tests lasted from 2 to 10 stages. After the initial testing session, subjects were provided with study instructions, including a set of activity logs to be completed and mailed to the researchers on a weekly basis. Subjects in the high- and low-intensity groups received an exercise prescription to be followed for the next 24 wk, whereas subjects in the control group were instructed to maintain their current level of activity.

TABLE 2. Sample exercise prescriptions.

Week	Sessions per Week	Low-Intensity Target HR[a] (% HRR)	High-Intensity Target HR[a] (% HRR)	Exercise Duration (min)
1	3	25	40	12
2	3	30	50	14
3	3	35	60	16
4	3	40	70	18
5	3	45	75	21
6–9	3	50	80	21
10–13	3	60	85	24
14–16	3	60	85	24
17–19	3	60	85	28
20–24	3	60	85	30

[a] Target HR (% HRR) = [(220 − age) − RHR] × prescribed % + RHR.

Exercise prescriptions for the low intensity group began at 25% HRR, increasing 5% per week for the initial 6 wk of the study. Percent HRR was calculated by the following formula:

$$[(220 - age) - RHR] \times prescribed\% + RHR$$

Exercise intensity remained at 50% HRR through week 9. At week 10, exercise intensity was increased an additional 10% to a maximum of 60% HRR, where it remained for the duration of the study. Exercise prescriptions for the high-intensity group began at 40% HRR, increasing 10% per week through week 4. Subsequent increases at weeks 5, 6, and 10 were in 5% increments up to a maximum of 85% HRR. Exercise intensity remained at 85% HRR for the duration of the study. Exercise duration was gradually increased for both exercise groups from week 1 to week 20, beginning at 12 min and reaching a maximum of 30 min, where it remained for the final 4 wk of the study. A sample exercise prescription for both low- and high-exercise intensity can be found in Table 2.

Statistical Analysis

Descriptive statistics were calculated on the dependent variables (i.e., HR, RHR, blood lactate, RPE, FIQ, BDI, SAI, HAQ-SDI, and HAQ pain index). A series of Student's *t*-tests were conducted to examine for significant group differences in the dependent measures at each of the three data collection periods. Because multiple *t*-tests were computed, Bonferroni adjustments were made to the alpha level (obtained by dividing 0.05 by the number of tests to be performed) to minimize the risk of making a Type I error (35). No statistically significant differences were found between groups on any of the physical or psychological measures at any of the three data collections.

Failure to detect statistically significant differences between groups, in conjunction with the small number of

subjects completing the study, prompted a collapse of the three subject groups. After collapsing the three subject groups, descriptive statistics were recalculated on the dependent variables. A second series of Student's *t*-tests with Bonferroni adjustment were conducted to examine for significant changes in the dependent variables over time. Plotting of means was performed to determine the shape of the relationship between exercise and the dependent measures when significant differences were found. Finally, omega squared values (ω^2) were calculated to provide an estimate of the magnitude of the treatment effects (35). The values of $\omega^2 > 0.20$ are considered large, >0.10 moderate, and >0.05 small (12).

Subject recordings of activity levels indicated poor compliance with the assigned exercise prescriptions. As such, subjects were reassigned to the study groups based upon their recorded activity levels. A new series of Student's *t*-tests with Bonferroni adjustment were conducted on the dependent variables to examine for significant differences between groups, as well as significant differences over time. As with the groups collapsed, plotting of means was performed when significant differences were found and omega squared values were calculated.

RESULTS

Original Subject Groups

A total of eight subjects completed the study. The remaining 13 subjects discontinued their participation for reasons including, but not limited to, aversion to the finger sticks, onset of plantar fascitis, and refusal to participate in any regular walking program. No statistically significant differences were found between subject groups (i.e., high-intensity, low-intensity, control) on any of the dependent variables at any of the three data collection periods.

Subject Groups Collapsed

The lack of statistically significant differences between groups, in conjunction with the small number of subjects completing the study, prompted a collapse of the three subject groups. There were no statistically significant differences found on any of the dependent variables across time with the exception of RHR and HR. Analyses revealed a statistically significant 11.2% increase ($P < 0.02$) in RHR from week 0 to week 24 and a 10% decrease ($P < 0.05$) in exercise HR from week 0 to week 12. Omega squared calculations indicate that exercise had a large impact on HR ($\omega^2 = 0.36$), and plotting of means revealed a U-shaped quadratic trend.

Although no statistically significant changes were detected in HAQ-SDI over time, analyses indicate a 54% decline in HAQ-SDI between week 0 and week 24, with omega squared calculations, suggesting that exercise had a large impact ($\omega^2 = 0.30$) on this decrease. Although the small sample size may have prevented the finding of statistical significance, a decline in HAQ-SDI indicates an increased ability to undertake ADLs, or to perform the ADLs with less assistance.

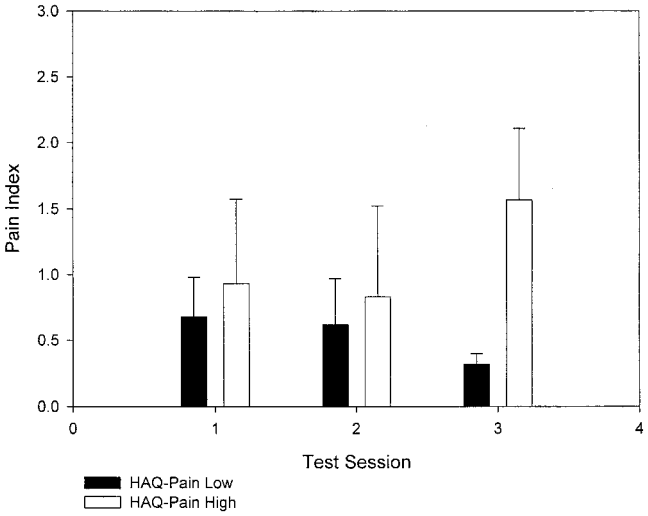

Figure 1—Changes in pain across time among reassigned high- and low-intensity exercise groups; ■, HAQ-pain low; □, HAQ-pain high.

Reassigned Groups

An examination of subjects' weekly logs revealed very poor compliance with the assigned exercise programs. As such, subjects were reassigned to the control group ($N = 0$), the low-intensity exercise group ($N = 5$), and to the high-intensity exercise group ($N = 3$) based upon the actual activity levels recorded in their logs. Note that the low- and high-intensity groups were exercising at approximately 50% HRR and 75% HRR, respectively.

Differences between reassigned groups. Although no significant differences between groups were found at any of the three data collection periods, differences in the pain score on the HAQ between the high- and low-intensity exercise groups approached significance, and may have reached significance with an increased sample size. Specifically, differences on the HAQ pain score approached significance at week 24, with pain being greater in the high intensity exercise group (see Fig. 1). Omega squared calculations indicate that exercise had a strong influence on pain ($\omega^2 = 0.51$). These results suggest that the pain experienced by individuals with FM may be influenced by the intensity of the exercise regimen in which they participated.

Differences over time. Significant changes in FIQ scores were found in both the high- and low-intensity exercise groups from week 0 to week 24. Whereas the FIQ score decreased 35% in the low-intensity exercise group ($P < 0.05$) from week 0 to week 24, an 8% increase in FIQ score was noted in the high-intensity exercise group ($P < 0.02$). Plotting of means revealed a linear trend in the low-intensity exercise group and a quadratic U-shaped trend in the high-intensity exercise group (see Fig. 2). Omega squared calculations indicated that exercise had a very strong impact on FIQ scores in both the low-intensity ($\omega^2 = 0.59$) and the high-intensity ($\omega^2 = 0.96$) exercise groups. These results suggest that whereas a low-intensity exercise

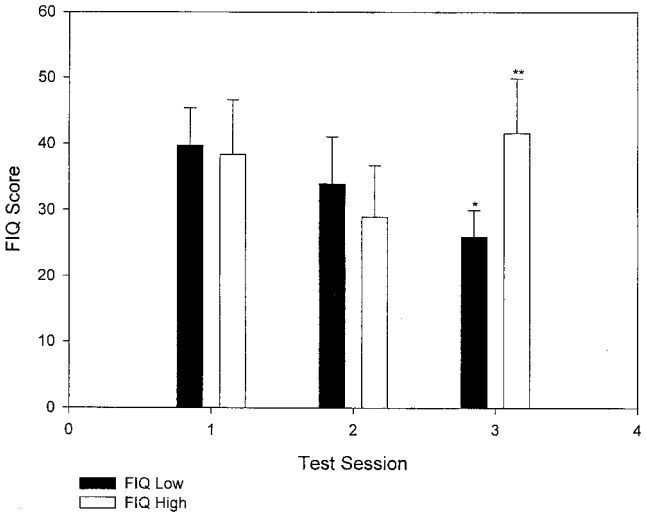

Figure 2—Changes in FIQ across time among reassigned high- and low-intensity exercise groups. *$P < 0.05$ and **$P < 0.02$ levels of significance; ■, FIQ-pain low; □, FIQ-pain high.

program may lessen the daily impact of FM, a more intensive exercise program may increase the impact of FM, resulting in greater disability.

DISCUSSION

Results of this study indicate that individuals with FM have the capacity to exercise at intensities sufficient to improve cardiovascular fitness. Specifically, in holding workload constant, HR at week 12 was significantly lower than at week 0. Because it is well known that one adaptation to aerobic training is an increase in stroke volume and decrease in HR at the same workload (19), it appears that subjects were able to exercise at an intensity sufficient to improve their cardiovascular fitness. Whereas the significant increase in RHR observed between week 0 and week 24 is not consistent with an improvement in cardiovascular fitness, this may have been confounded by the use of two different methods of measurement. Palpation was used during week 0 to instruct subjects in heart rate monitoring, whereas an electronic heart rate monitor was used at weeks 12 and 24. There was no such influence on HR, however, as the heart rate monitor was used at all three data collection periods. It appears that subjects became more fit from week 0 to week 12, the period when compliance was at its highest level. Although there has been some question as to the ability of individuals with FM to participate in a regular exercise program, the findings of this study and others (18,21,22) demonstrate that individuals with FM can be physically active at levels sufficient to result in an aerobic training effect.

Although the absence of a significant change in blood lactate and RPE and the upward trend in HR from week 12 to week 24 do not support the above assertion, the small number of subjects completing the study may have prevented the finding of significant differences over time. RPE is affected by environmental conditions, such as air temperature (17,33) and time of day (14), and therefore it is possible that differences in the environmental conditions on the 3 days of testing may have been sufficient to negate changes in RPE associated with training. Oxygen uptake ($\dot{V}O_2$) may be a more appropriate tool for use in future studies. The upward trend in HR noted from week 12 to week 24 may be explained by a reduced rate of compliance with the exercise program by some subjects during the final 12 wk of the study. Specifically, a lapse in the frequency, duration, or intensity of the exercise program may be associated with a reversal in the HR changes noted previously.

The short-term change in cardiovascular fitness discussed above contradicts the apparent change in the impact of FM upon subject's daily lives after 24 wk of exercise. Although not significant, possibly due to the small number of subjects, a 54% decline in the HAQ-SDI from week 0 to week 24 suggests that following a 24-wk walking program, individuals with FM have an increased ability to perform their ADLs, and to do so with less assistance. This change may be partially explained by an improvement in cardiovascular fitness; however, the lack of continued improvement in fitness from week 12 to week 24 indicates that other factors were also involved. Likewise, a reduction in pain would not appear to explain this phenomenon, as no significant reduction in pain was found.

Along with the decline in HAQ-SDI, subjects reassigned to the low-intensity exercise group demonstrated a significant decrease in FIQ scores from week 0 to week 24. Although subjects reassigned to the high-intensity group did not record a significant reduction, plotting of means indicated a trend toward a reduction in FIQ at week 12 (see Fig. 2). These results suggest that FM may have had less of an impact on the subjects' daily activities at week 12 than at week 0. This was not the case at week 24, however, where an 8% increase in FIQ score over week 0 was noted in the high-intensity group, indicating a greater impact of FM upon their daily activities. Thus, it appears that whereas exercising at a high intensity is tolerated for a limited duration over a short period of time, prolonged exposure to a high-intensity exercise regime is not well tolerated and may have an adverse effect on function. On the other hand, exercising at a low-intensity level is well tolerated and may be associated with improved function as adherence continues.

That the results of the current study did not reflect a reduction in pain following a regular program of walking is inconsistent with previous research (18,21,22,27). The low-intensity levels at which most of the subjects were exercising may have been insufficient to stimulate the production and release of the quantities of adrenocorticotropic hormone, beta-endorphin, and/or serotonin thought necessary to produce reductions in pain (20,27). Similarly, the duration of exercise (i.e., 20–30 min) may have been insufficient to facilitate an increase in serotonin release (13). This may be further compounded by reduced levels of serotonin precursors (24,32,38). Although the use of an absolute quantification of exercise intensity (i.e., 115 bpm) rather than a

relative quantification of exercise intensity (i.e., % HRR) makes it difficult to compare studies, it would appear that insufficient exercise intensity is not a likely explanation for the results of the current study. The fact that heart rates in the low to moderate range were used in studies that reported decreases in pain suggests that participation in physical activity of low to moderate intensity levels may be most appropriate in reducing FM-related pain.

Another possible explanation for the lack of pain reduction in the current study may be that subjects were exercising at intensities that were too high, therefore inducing muscle microtrauma and increased pain (6,27). This may be especially true of the high-intensity group and may explain why differences in HAQ pain scores between the high-intensity and low-intensity groups approached significance at week 24 (see Fig. 1).

As with pain, the absence of change in the psychological measures is also inconsistent with previous literature, which suggests that anxiety (25,36) and depression (16,31) decrease in individuals participating in a program of regular exercise. As such, the lack of change in anxiety levels in the current study may have been influenced by the small number of subjects completing the study, as well as by poor compliance with the exercise prescriptions (i.e., frequency and intensity) demonstrated by several of the subjects. In terms of the other psychological variable of interest, depression, it has been suggested that exercise may be more effective in decreasing depression in psychologically clinical populations as opposed to psychologically normal populations (28). Because all subjects in the current study recorded BDI scores in the minimal (0–9) to mild (10–16) range, their already positive affect may have created a "floor effect," thereby providing further explanation for the absence of change (i.e., decrease) in this psychological variable.

The small sample sizes in the current study were the result of a high attrition rate and poor compliance with the exercise prescription. The failure of a large number of subjects to complete the study and the self-modification of the exercise prescriptions indicate the need for direct supervision of exercise when working with this population. This is true for both the clinician and the researcher. Although these issues are not unique to this study (18,21,22), the small number of subjects completing the study increases the likelihood of making a Type II error. Other methodological issues that need to be addressed in future research include the use of a consistent definition of exercise intensity, and an examination of exercise at a lesser frequency (e.g., two times per week rather than three times per week). Because subjects appear to self-select two times per week as a preferred exercise frequency (18), compliance with the exercise prescription may be greater at this reduced frequency. An examination and comparison of different modes of exercise is also an important area of research yet to be fully developed.

The results of this pilot study indicate that individuals with FM have the ability to adhere to an exercise regime of an intensity and duration sufficient to meet American College of Sports Medicine (ACSM) guidelines for improvement in aerobic fitness (1) and to reduce the impact of FM upon their daily activities. Although the effect of exercise on pain is less clear, both the intensity and duration of the training program appear to be important to its outcome. Whereas adherence to a 24-wk low-intensity exercise regime may reduce the impact of FM on ADLs, exercise of 12-wk duration appears insufficient to improve function. Alternatively, although short-term participation in a high-intensity exercise program may be adequately tolerated, prolonged participation in a regime of high-intensity exercise may result in increased disability. Therefore, individuals with FM may benefit from a prescription of 30-min of supervised low-intensity walking, two to three times per week. A replication of the current pilot study of larger scope is needed to clarify the responses of individuals with FM to exercise of various intensities and frequencies. Methodological issues to consider include a larger sample size, standardization of data collection procedures, including the use of dolorimetry (i.e., a device that can reproducibly measure the degree of sensitivity present) for TP assessment, the addition of $\dot{V}O_2$ measurement to assess change in cardiovascular fitness, and supervision of the exercise program to improve subject compliance.

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