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Effects of Lifestyle Physical Activity in Adults With Fibromyalgia:

Results at Follow-Up

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Abstract

Background—In a 12-week randomized controlled trial of the effects of lifestyle physical activity (LPA) on symptoms and function among adults with fibromyalgia, we found that LPA participants increased their average daily step count by 54%, improved their self-reported functioning by 18%, and reduced their pain by 35%.

Objectives—The objective of the study was to evaluate the intermediate (6 months) and long-term (12 months) effects of the LPA intervention on outcomes.

Methods—Participants completed follow-up assessments of physical activity, pain, fibromyalgia-related function, fatigue, depression, number of tender points, 6-minute walk test, and perceived improvement at 6 and 12 months after intervention.

Results—Of the 73 participants who completed the 12-week trial, 53 (73%) completed both the 6- and 12-month follow-up. Although the LPA participants reported greater perceived improvement at each follow-up, they did not differ from controls on pain, physical activity, tenderness, fatigue, depression, or the 6-minute walk test. Self-reported functioning declined markedly at follow-up for the LPA participants.

Conclusions—Although participants reported greater perceived improvement at each assessment, the beneficial effects of LPA on physical activity, function, and pain found after the 12-week intervention were not sustained over time. This recidivism is seen in studies of activity and exercise in nearly any condition, and innovative methods that may prevent this are a focus of future studies.

Keywords

fibromyalgia; physical activity; pain

Fibromyalgia (FM), a chronic, multidimensional disorder characterized by persistent, widespread body pain and tenderness,¹ affects about 2% of the US population and occurs about 8 times more in women than in men.² Fibromyalgia can hamper day-to-day functioning and is a major cause of disability.³ In a previous report,⁴ we evaluated the effects of 12 weeks of lifestyle physical activity (LPA; it involves working toward meeting

the US Surgeon General's 1996 Physical Activity Recommendations⁵ of accumulating at least 30 minutes, above one's usual activity, of moderate-intensity physical activity 5–7 days a week by integrating short bouts of activity into the day, such as increasing the amount of walking, performing more yard work, or using the stairs) on pain, function, fatigue, and other outcomes in adults with FM. We found that, compared with education controls, the LPA participants increased their average daily step count by 54%, reduced their functional deficits, as assessed by the Fibromyalgia Impact Questionnaire⁶ (FIQ), by 18%, and reduced their pain by 35%. In this article, we report the results of 6- and 12-month follow-up assessments of physical activity, pain, functional deficits, fatigue, depression, tender points, 6-minute walk test, and perceived improvement.

PATIENTS AND METHODS

Study Participants

Seventy-three participants (70 women and 3 men) 18 years or older who met American College of Rheumatology diagnostic criteria⁷ for FM completed the 12-week trial. The mean (SD) age of participants was 47.2 (11.1) years, and 84% were white. The mean duration of FM was 7.4 (6.2) years. Detailed inclusion/exclusion criteria, study procedures, and descriptions of the LPA intervention were described previously.⁴ In brief, participants assigned to LPA attended six 60-minute group sessions over 12 weeks designed to increase moderate-intensity physical activity by helping participants find ways to accumulate short bouts of physical activity throughout the day. Participants assigned to the fibromyalgia education (FME) control group met monthly for 3 months and were provided a minimal intervention that provided FM education and social support.⁴

Assessments

At each of the 4 assessments (i.e., baseline, postintervention, 6- and 12-month follow-up), participants completed a series of questionnaires, a tender point examination, and a 6-minute walk test. The questionnaires were the 10-item FIQ,⁶ a 100-mm pain visual analog scale, the 7-item Fatigue Severity Scale,⁸ and the 20-item Center for Epidemiologic Studies Depression Scale (CES-D).⁹ A digital tender point examination, at the 18 sites specified in the American College of Rheumatology FM classification criteria,⁷ was also completed at each assessment. For the 6-minute walk test,¹⁰ participants walked as far they could in 6 minutes on a preselected course, with the distance walked recorded. At postintervention and at 6- and 12-month follow-up, they also completed a single-item measure that asked, "Since the start of the study, how much change has there been in your FM?" Responses were on a 7-point scale ranging from "very much better" to "very much worse," with lower scores indicative of greater perceived improvement. Finally, for each assessment, participants wore a waist-mounted pedometer (AccuSplit Eagle 1020, Livermore, California) for 7 days (recalibrating it each morning) and recorded their daily step count (these data were used to calculate the mean steps per day as an estimate of physical activity).

Data Analysis

Changes on physical activity (i.e., average daily steps) and outcome measures from baseline at postintervention and at 6- and 12-month follow-up were examined using a 2×4 (condition $\times$ time) repeated-measures analysis of variance and, when appropriate, post hoc comparisons on the participants who completed each follow-up assessment. Participants with missing data on 1 of the 4 physical activity assessments ($n = 17$) or on any outcome measures ($n = 5$) were included in the analysis by using their last observation carried forward. Because there was a significant difference between the LPA and FME groups on self-reported duration of FM, this variable was included as a covariate. Changes in medication (i.e., 0 = no change, 1 = change), queried at each assessment, were also included

as a covariate in the models. Analyses were performed using SPSS software, version 16 (SPSS Inc, Chicago, Illinois). Two-tailed $P < 0.05$ was used to denote statistical significance.

RESULTS

Fifty-three of the 73 participants (73%) who completed the 12-week intervention also completed the 6- and 12-month follow-up assessments. Failure to complete the follow-up assessments was unrelated to randomized treatment assignment ($P = 0.657$), and there were no significant differences on any study variables between those who did or did not complete the follow-up assessments (data not shown). With the exception of duration of FM, the LPA and FME groups were comparable on age, race, education, and employment status or in medication changes during the trial (Table 1).

Figure 1 shows average daily step counts during the four 7-day assessments for the LPA and FME groups. There was significant effect for condition ($P = 0.038$), but not for time ($P = 0.197$) or time $\times$ condition interaction ($P = 0.117$). The effect of condition was driven by a significant baseline to postintervention difference between LPA and FME ($P = 0.002$). Table 2 shows the results of the repeated-measures analysis on study outcomes. There was no significant condition or time effects on the FM Impact Questionnaire (FIQ) scores. However, there was a significant condition $\times$ time effect ($P = 0.022$) between comparisons of LPA and FME at baseline to postintervention and at postintervention to the 6-month follow-up assessments (P 's = 0.008 and 0.015, respectively). Specifically, the beneficial effects of LPA on FIQ scores found at the baseline to postintervention comparison with FME were not maintained at 6-month follow-up. Indeed, the LPA group's FIQ scores increased at 6-month follow-up, whereas they decreased for FME. There was a significant time effect ($P = 0.003$) for CES-D scores, which was driven by a significant reduction in the scores for both groups between their postintervention and 6-month follow-up assessments ($P = 0.009$). There was also a significant condition effect ($P = 0.001$) on the perceived improvement variable indicating that LPA participants reported significantly greater improvement than did FME participants at postintervention and at 6- and 12-month follow-up (P 's = 0.001, 0.020, and 0.014, respectively).

DISCUSSION

Among the 53 patients who completed all assessments, the significant effects of LPA on physical activity, function, and pain found during the 12-week trial were not maintained at 6- and 12-month follow-up. The absence of sustained benefits at follow-up is consistent with the vast majority of studies on the effects of lifestyle intervention pertaining to, for example, weight loss and diabetes management.^{11,12} In FM exercise studies, attrition rates are relatively high, and adherence rates are relatively low,¹³ with patients reporting that pain and beliefs that exercise worsens their symptoms as primary impediments to maintaining an exercise regimen.¹⁴ Based on feedback from our study participants, the primary challenge of the LPA intervention was consistently (i.e., 5–7 d/wk) engaging in moderate-intensity physical activity, given the fluctuating nature of FM symptoms, particularly the fatigue and stiffness. That is, participants would have periods where their symptoms were quiescent so they could string together days of consistently elevated physical activity. However, during a period of increased symptoms, they found it difficult to adhere to the prescribed level of LPA. It is important to note, however, that although there was no statistically significant time or time $\times$ condition effect, the LPA group had an average daily step count at 12-month follow-up that represented a 44% increase from their baseline level of physical activity (the FME group, which did not receive information on the value of physical activity for FM until

their last group session, increased their physical activity by 26% compared with their baseline level).

Interestingly, despite the absence of significant differences on outcomes at follow-up between the groups, the LPA participants perceived significantly greater improvement in their FM at each assessment compared with FME. It is possible that it is the result of developing a greater sense of self-efficacy as a function of participating in a trial that required tangible changes in behavior (e.g., self-monitoring of physical activity). This is conjecture, however, as self-efficacy was not assessed in this study.

Limitations of this study include the relatively small sample of participants who completed all follow-up assessments; the use of an education, as opposed to a nontreatment control group; and the use of pedometers to assess physical activity. Despite these limitations, the results of this study suggest that the effects of LPA are not well sustained over time. Given the evidence suggesting that exercise and physical activity can be beneficial for people with FM,^{13,14} additional strategies and innovative approaches need to be developed to assist these patients in staying physically active.

For example, we think the LPA program could be significantly improved by encouraging and promoting increased interaction between participants and between participants and study staff between group meetings and during follow-up. In particular, the use of a study-specific Web site, where patients could have additional access to resources and could communicate with study staff and other participants, might assist them in staying physically active. Participants could also enter their step counts on the Web site to track their levels of physical activity overtime. This form of interactive self-monitoring might facilitate greater adherence. Moreover, the use of prompts, words of encouragement, and tailored messages sent to patients' e-mail accounts might be useful to help them stay as physically active as the waxing and waning of their FM symptoms allow. Finally, the Web site could facilitate social networking to allow the participants to interact with each other and share advice and provide social support. Indeed, one of the authors (D.J.C.) has been involved in the development of such a Web site (www.knowfibro.com) to help patients better manage their FM¹⁵ (see also Lorig et al.¹⁶). The incorporation of Internet-based technologies to both deliver treatment and facilitate its adherence have also been applied to obesity (e.g., see Funk et al.¹⁷ and Arem and Irwin¹⁸), physical activity promotion,^{19,20} and smoking cessation,²¹ with some success. Innovative strategies such as these need to continue to be developed and refined to increase the chances that lifestyle modifications can be maintained in the intermediate and long term.

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Assessment	LPA	FME
Baseline	3189 ± 1958	3094 ± 1877
Post	5648 ± 3564	3752 ± 1897
6 Months	4496 ± 3228	4142 ± 2286
12 Months	4589 ± 3190	3897 ± 2460

FIGURE 1.
Average daily steps for the two study groups during each 7-day assessment.

TABLE 1Characteristics of the 53 Adults With FM Who Completed the 6- and 12-Month Follow-Up Assessments^a

Characteristic	LPA	FME	P
No. (%) of participants	30 (56.6)	23 (43.3)	
Age, mean (SD), yrs	47.5 (12.5)	47.8 (11.8)	0.913
Female, n (%)	27 (90)	23 (100)	0.173
Self-reported race, n (%)			0.646
White	26 (86.7)	20 (87)	
Nonwhite	4 (13.3)	3 (13)	
Marital status, n (%)			0.297
Married or cohabitating	13 (43.3)	15 (65.2)	
Widowed, divorced, or separated	9 (30)	6 (26)	
Single	8 (26.7)	2 (8.7)	
Educational level, n (%)			0.369
Postgraduate	13 (43.4)	4 (17.4)	
College graduate	6 (20)	6 (26.1)	
Some college	7 (23.3)	9 (39.1)	
High school	4 (13.3)	4 (17.4)	
Employment status, n (%)			0.354
Employed	11 (36.7)	9 (39.1)	
Unemployed or disabled	8 (26.7)	5 (21.7)	
Retired or other	11 (36.7)	9 (39.1)	
Years since diagnosis, ^a mean (SD)	5.8 (5.3)	9.3 (7.4)	0.050
Any medication change, n (%)	20 (66.7)	14 (60.9)	0.775

^aData for categorical variables are presented as n and percentages; data for continuous variables are presented as means (SD).

TABLE 2

Repeated-Measures Analysis of Differences Between LPA and FME Groups on Outcomes

Variable	Mean (SD)		<i>p</i> ^a		
	LPA	FME	Condition Effect	Time Effect	Time × Condition
FIQ					
Baseline	67.2 (13.1)	66.2 (13.4)	0.685	0.148	0.022
Postintervention	55.6 (18.7)	67.1 (19.9)			
6-mo follow-up	65.3 (17.0)	63.9 (24.5)			
12-mo follow-up	64.4 (20.9)	65.1 (25.8)			
Pain VAS					
Baseline	57.7 (23.7)	53.4 (25.2)	0.787	0.847	0.117
Postintervention	48.4 (23.2)	60.0 (25.4)			
6-mo follow-up	54.9 (21.0)	49.4 (27.1)			
12-mo follow-up	51.6 (22.0)	50.9 (27.2)			
Fatigue Severity Scale					
Baseline	52.1 (6.9)	52.3 (10.2)	0.978	0.642	0.282
Postintervention	52.0 (9.4)	50.6 (10.4)			
6-mo follow-up	48.4 (8.6)	51.0 (7.3)			
12-mo follow-up	49.0 (10.1)	49.7 (11.9)			
CES-D score					
Baseline	23.8 (8.5)	21.9 (10.8)	0.893	0.003	0.194
Postintervention	22.1 (10.2)	20.7 (11.0)			
6-mo follow-up	18.1 (8.1)	19.9 (12.5)			
12-mo follow-up	19.8 (10.1)	20.6 (12.9)			
No. of tender points					
Baseline	16.4 (2.2)	16.3 (2.0)	0.337	0.503	0.270
Postintervention	16.3 (1.8)	16.6 (2.2)			
6-mo follow-up	15.4 (3.2)	16.3 (2.0)			
12-mo follow-up	15.3 (3.0)	16.3 (2.2)			
6-min Walk test, ft					

Variable	Mean (SD)			<i>p</i> ^a		
	LPA	FME		Condition Effect	Time Effect	Time × Condition
Baseline	1284 (157)	1308 (260)	]			
Postintervention	1503 (378)	1356 (263)				
6-mo follow-up	1351 (251)	1336 (375)		0.976	0.065	0.132
12-mo follow-up	1340 (159)	1415 (211)				
Perceived improvement ^b						
Postintervention	3.3 (1.0)	4.3 (0.81)	]			
6-mo follow-up	3.4 (1.2)	4.2 (0.99)		0.001	0.751	0.596
12-mo follow-up	3.2 (1.2)	4.0 (1.4)				

^aBased on repeated-measures analysis of variance, which included all data collection periods (baseline, postintervention, 6-month follow-up, 12-month follow-up).

^bNot assessed at baseline.

VAS, visual analog scale.