The Effectiveness of Multidisciplinary Rehabilitation in the Treatment of Fibromyalgia

A Randomized Controlled Trial

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Objectives: To assess the effectiveness of multidisciplinary rehabilitation in the treatment of fibromyalgia in comparison to standard medical care.

Methods: Seventy-nine men and women were randomly assigned to one of two groups. The intervention group consisted of a rheumatologist and physical therapist intake and discharge, 18 group supervised exercise therapy sessions, 2 group pain and stress management lectures, 1 group education lecture, 1 group dietary lecture, and 2 massage therapy sessions. The control group consisted of standard medical care with the patients' family physician. Outcome measures included self-perceived health status, pain-related disability, average pain intensity, depressed mood, days in pain, hours in pain, prescription and nonprescription medication usage, and work status. Outcomes were measured at the end of the 6-week intervention and at 15-month follow-up.

Results: Thirty-five out of 43 patients from the intervention group and 36 out of 36 patients from the control group completed the study. There were no statistically significant differences between the 2 groups prior to intervention. Intention-to-treat analysis revealed that the intervention group, in comparison to the control group, experienced statistically significant changes at intervention completion in self-perceived health status, average pain intensity, pain related disability, depressed mood, days in pain, and hours in pain, but no significant differences in nonprescription drug use, prescription drug use, or work status. At 15 months, all health outcomes retained their significance except health status. Nonprescription and prescription drug use demonstrated significant reductions at 15 months. Binary logistic regression indicated that long-term changes in Pain Disability Index were influenced by long-term exercise adherence and income status.

Conclusions: Positive health-related outcomes in this mostly unresponsive condition can be obtained with a low-cost, group multidisciplinary intervention in a community-based, nonclinical setting.

Key Words: fibromyalgia, randomized controlled trial, multidisciplinary, effectiveness

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Fibromyalgia is an ever-increasing concern in western and industrialized countries.[1] Chronic widespread musculoskeletal pain and multiple tender points characterize this syndrome with an unknown etiology.[2] Population-based estimates of the prevalence of the disorder generally range from 0.5% to 5.8%,[3–9] although the prevalence of chronic widespread pain alone is considerably higher.[4,10] There can be wide variability in prevalence from one neighboring country to the next, and the disorder has generally not been identified or at least well studied in nonindustrialized nations or cultures.[11,12] These differences have been assumed to be at least partially the result of diagnostic settings and labeling, social awareness, and disability insurance incentives rather than any real differences in morbidity pattern,[11,13,14] although opposing views do exist.[7] At this time, the variables of female sex, older age, low education attainment, lower social status, and psychologic distress appear to be associated with this disorder on a population-based level.[4–7,9,15]

Because the etiology is unknown, treatment of fibromyalgia is mostly symptomatic. Many pharmacologic, physical, and other therapies have been widely used to treat this disorder, although scientific evidence of their effectiveness is still lacking.[1] For that reason, the physical rehabilitation of musculoskeletal disorders has been combined with psychologic, behavioral, and educational interventions.[1] This multidisciplinary treatment is practiced in pain clinics and rehabilitation centers, which have rapidly increased in number over the last few decades.[1,16] Unfortunately, the effectiveness of these centers has rarely been tested specifically for fibromyalgia let alone the cost effectiveness.[1] A recent systematic literature review of 1808 abstracts concluded that there appears to be little

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scientific evidence supporting the effectiveness of multidisciplinary rehabilitation for fibromyalgia and chronic widespread musculoskeletal pain. The reviewers did find some benefit, however, in seven papers with behavioral treatment, stress management, patient education, and physical exercise, although higher quality randomized trials in the field would be required to confirm their effectiveness.[1] Other meta-analyses suggest that nonpharmacologic management of fibromyalgia has more efficacy than pharmacologic management,[17] with the most evidence supporting cognitive behavior therapy and, to a greater extent, general aerobic exercise.[17,18]

In response to the findings of these 3 meta-analyses, a prospective, randomized controlled trial was designed to test the effectiveness of multidisciplinary rehabilitation in a low-cost, group nonclinical setting in comparison to standard medical care. The primary outcomes were health status, average pain intensity, pain-related disability, depressed mood, days in pain, hours in pain, medication usage, and work status between the two groups. Secondary outcomes included determining if change in health outcome at intervention completion was due to active stage of change instead of randomized group allocation and if long-term changes in health outcome were due to continued exercise adherence. Binary logistic regression was used in an attempt to describe the relationship between the outcome variable of long-term Pain Disability Index (PDI) change and potential explanatory variables. The methodology of the trial was based on the recommendations listed by the CONSORT statement.[19]

MATERIALS AND METHODS

Study Design and Subjects

A trial project of 20 cases was initiated prior to the randomized trial to determine protocol effectiveness, adherence, safety, and the validity and reliability of the questionnaire (same health outcomes as current study). These cases were not included in the randomized trial. Upon completion of the trial project, a letter was sent to every family physician within city limits asking them to refer patients to the research protocol. Eligible subjects required: 1) a referral from their physician indicating that their patient was believed to have fibromyalgia and was safe to participate; 2) chronic (6 months not 3 months) widespread pain in at least 3 quadrants of the body and at least 11 tender points out of 18 when a pressure of approximately 4 kg was applied[2]; and 3) be 18 years of age or older to give written informed consent. Patients were to be excluded if their pain was of a malignant nature. Patients were not excluded for any other comorbidity.

Eighty-two potential subjects were referred. Three patients indicated that they were not interested in participating. Seventy-nine men and women were randomly assigned to 1 of 2 groups each with a 6-week duration. The intervention group consisted of a rheumatologist and physical therapist intake, 18 group supervised exercise therapy sessions, 2 group pain and stress management lectures, 1 group education lecture, 1 group dietary lecture, 2 massage therapy sessions, and at the end of the program a rheumatologist and physical therapist discharge. The initial rheumatologist evaluation was intended to obtain a detailed history, confirm the diagnosis of fibromyalgia,[2] and verify appropriateness to participate. It was also intended to develop a management plan with the patient including encouragement to limit medication usage, promote long-term lifestyle changes, create realistic expectations, promote the importance of full active participation, and communicate with the family physician. The physical therapist was to provide a detailed biomechanical evaluation, provide education on hurt versus harm, identify barriers to participation, and initiate an action plan to prevent dropout. The physical therapist did not provide mobilization or manipulation techniques or passive therapies. The exercise therapist was responsible for supervising the exercise therapy sessions, which included submaximal aerobic exercise (5 minutes initially of 50% max oxygen consumption [VO_2] treadmill progressing to 20 minutes at 6 weeks), stretching before and after weight training (5 minutes lower body and 5 minutes upper body), and light weight training (2 sets of 15 repetitions with the leg press, leg extension, seated row, and lat pulldown machines beginning in weight with 10 and progressing to 30 pounds). The exercise therapist was also responsible for monitoring attendance and creating a social, nonintimidating environment for the patients. The PhD level psychologist provided 1 3-hour group lecture on relaxation training and another 3-hour group lecture on behavioral modification including pain and stress management. Both group sessions were lecture format and practical to transfer information (educational style in comparison to traditional one-on-one therapeutic style). The rheumatologist was also responsible for providing a 3-hour general management and education lecture on fibromyalgia that encouraged active management approaches and concluded with a question and answer session. The rationale for patient education, behavioral management, stress management, and physical exercise was based on the conclusions of 3 recent systematic literature reviews.[1,17,18] The dietician was to provide 1 3-hour group lecture on general dietary goals and strategies to attain them. The massage therapist was to provide 2 20-minute individual sessions with the goal being more relaxation and a means of reward after initial exercise sessions than any type of therapeutic benefit. There was no rationale, other than possible patient satisfaction, for the dietary or massage interventions. There was no vocational or return to work component. The waiting list control group consisted of standard care with the patient's family physician. The control intervention included medical specialist referral (8%), referral to treatment (53%), education (3%), medication (22%), further diagnostics (3%), and nothing at all (11%). The unit of randomization was individual, computer-generated, and envelope concealed. This process, as well

as intervention allocation, was under the supervision of a data manager. Blinding of patients and therapists to treatment status was not considered possible so treatment credibility was evaluated in both patients (questionnaire) and therapists (interview) prior to intervention. Therapists were blind as to which of the many outcome variables were primarily under evaluation and were unaware of any specific hypotheses concerning outcomes. As such, the therapists could not decide to prioritize any one health outcome at the expense of another (ie, function over pain). All 3 intervention groups occurring at different times had the same treatment practitioners and followed the same written protocol. No evaluation, however, was provided to ensure that the therapists actually adhered to the protocol, although there is no evidence to suggest this did not occur. The outcome assessor (principal investigator) was blind to the intervention status during both the trial and analysis. Additional treatments or interventions other than family physician were discouraged during the trial but were measured if not adhered to. The trial was terminated for any one participant if any medical condition prohibited safe continuance. There was no direct or indirect charge to the patients for the research protocol.

The intervention was to occur in a local YMCA to promote a social, nonclinical, nonintimidating environment that attempted to avoid a "white coat syndrome." The primary components of the intervention were submaximal general exercise, education, lifestyle changes, and self-management. Active participation was maximized with supervised visits, phone calls with every absence, and scheduled attempts to determine knowledge retention. The patients were involved in developing their own management plan, developing realistic short-term expectations, and identifying barriers to recovery and management.

Outcome Measures

Written questionnaires were completed at the time of randomization and at the completion of the 6-week intervention. A phone questionnaire was conducted at 15 months (by the exercise therapist) after the completion of the intervention. Before and after blinded measurements were taken for the following: health status from 1 (excellent health) to 5 (poor health),[20] average pain in the last month from 0 (no pain) to 10 (pain as bad as it can be) (Visual Analog Scale[21]), 7 questions on how chronic pain impacts in their everyday life including family, recreation, social activity, occupation, sexual behavior, self care, and life support activity (Pain Disability Index[22]), 21 statements that best describe their feelings within the last 2 weeks (Beck Depression Inventory [BDI] II[23]), days in pain and hours in pain without relief in the last 30 days, prescription and nonprescription drug usage in the last 30 days, and work status. Stage of change was measured prior to the intervention by way of questionnaire.[24] This questionnaire is relevant to over 12 problem behaviors including chronic rheumatoid arthritis and osteoarthritis[25] but has never been validated specifically for a fibromyalgia population. The authors substituted the word fibromyalgia where appropriate in the original questionnaire.

Statistical Analysis

χ^2 tests were used for comparisons of categorical variables and analysis of variance for comparisons of continuous variables to determine baseline differences between the 2 groups. A priori sample size determination indicated that 36 patients would be required to complete each group to detect a difference (beta of 0.80, alpha of 0.05, difference of 10, and standard deviation of 15). The intention-to-treat principle was used to compare the intervention and control groups. Dropouts were coded as having no improvement or regression in health outcome from baseline. Independent sample *t* tests were used to compare the absolute difference in the means between the 2 groups in all measurements except change in work status in which a χ^2 test was used. Ninety-five percent confidence intervals (95% CIs) were also built around the mean absolute difference between the 2 groups. Greater weight was placed on reviewing the CIs and limits, in comparison to the *P* values, when determining whether or not the intervention had a significant effect on health outcome.[26] Multiple comparison adjustment (ie, Bonferroni) was not used. Although valid in preventing alpha-type errors, these methods are known to substantially increase beta type errors and imprecision.[26] Independent sample *t* tests were used to determine if the changes observed between the intervention group and the control group were a result of stage of change in both groups rather than randomized group allocation. Paired *t* tests were used to determine if the changes observed in the intervention group at intervention completion retained their significance at the 15-month follow-up (no comparison to control group at long-term follow-up). Independent sample *t* tests were also used to determine if long-term changes observed in the intervention group were a result of continuing on with the scheduled exercise program in comparison to quitting.

Multivariate adjustment (binary logistic regression) was used in an attempt to describe the relationship between the outcome variable of long-term PDI change (defined as above or below the mean change of 15 points on the scale from baseline representing both statistical and clinical change) and the potential explanatory variables. To accommodate for sample size, a hierarchal well-formulated front-wise modeling approach was used instead of a computer generated stepwise algorithm.[26] The unadjusted effect of each covariate was determined and then entered one step at a time based on changes in the −2 log likelihood and the Wald test.[26] The final model includes factors with beta values for which the *P* values were less than 0.05. Confounding was tested by comparing the estimated coefficient of the outcome variable from models containing and not containing the covariates.[26,27] Interaction was tested with product terms.[26,27] R^2 was used to determine the propor-

tion of variance in the outcome variable explained by the knowledge of the explanatory variables but not as a measure of the appropriateness of the final model.[26,27] Goodness-of-fit of the final model was assessed by the Hosmer-Lemeshow statistical test.[27] The final results are presented as adjusted odds ratios (ORs) with 95% CIs. All analyses were performed with an SPSS 10.0 software package.[28]

RESULTS

Participant Flow

Forty-three subjects began the intervention group, and 36 subjects began the control group. Seven subjects quit the intervention protocol prior to completion (16.3%). Six subjects quit within the first 2 weeks citing lack of time as a reason. One subject quit the intervention due to complications with a medical condition not related to the study. In total, 36 subjects completed the 6-week intervention, and all 36 subjects completed the control (Fig. 1). Thirty-five intervention subjects out of 36 completed the 15-month follow-up on the intervention group (1 moved to unknown new location). There was some difference between those that completed the program and those that quit in stage of change, but the results were not statistically significant (likely due to lack of sample size). Three separate intervention groups and 2 separate control groups began the protocol from January 1, 2001 to June 15, 2001. Patient recruitment began 1 month before the initiation of the trial and continued until June 15, 2001. All interventions were completed by July 31, 2001. Fifteen-month follow-up information was collected on each intervention group upon completion of the intervention with a study completion date of October 31, 2002.

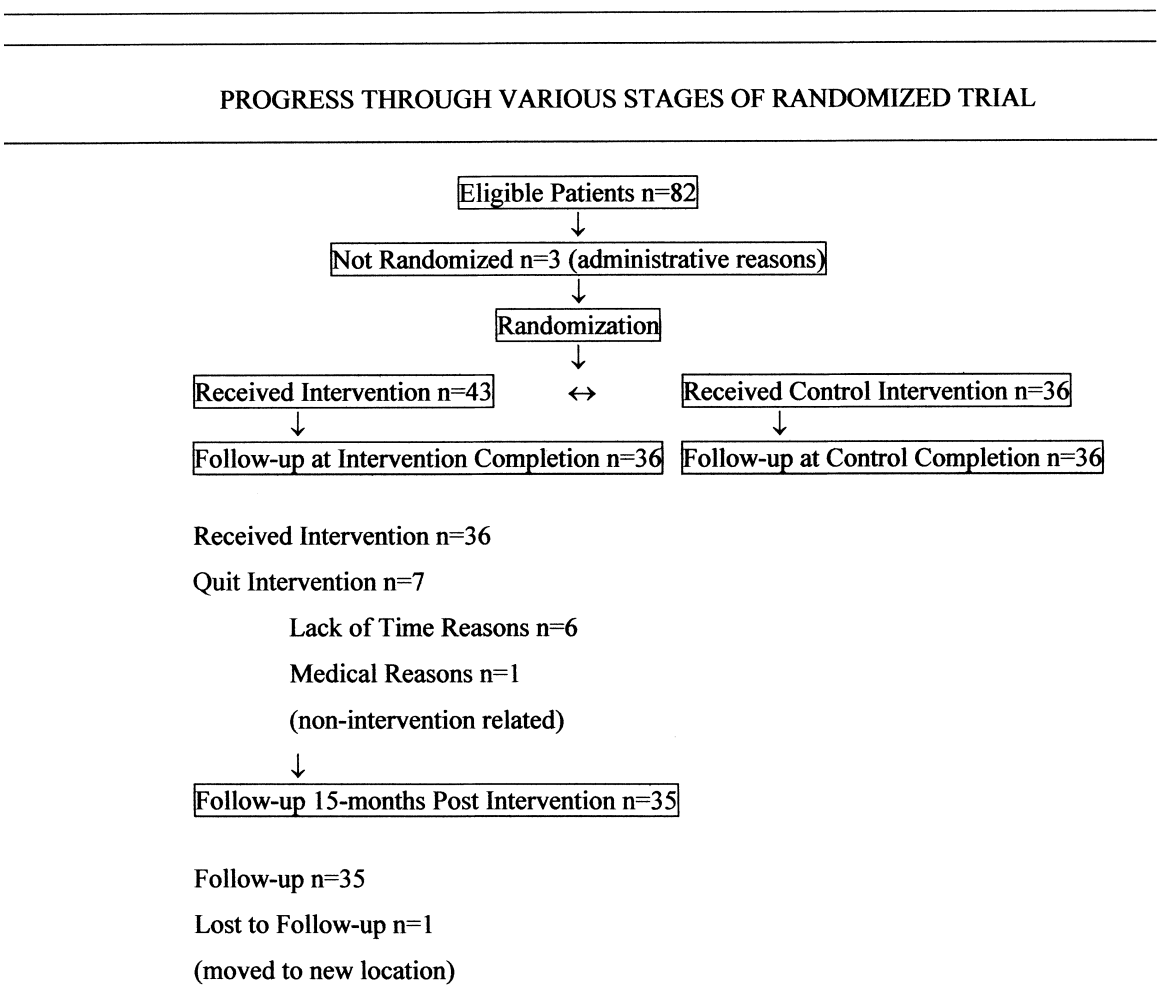

FIGURE 1. Progress through various stages of the randomized trial.

Characteristics of the Subjects

The baseline demographic, clinical, and psychologic characteristics between the intervention group and the control group were similar (Table 1). Highlights in the intervention group include 121.7 months of previous pain, mean depressed mood levels higher than 16 (18.2) suggesting marked depressed mood for the entire group, and only 23.3% of the group expecting that the intervention would help, although the entire group was at least prepared to make small changes to aid in their rehabilitation. In comparison, the control group included 120.6 months of previous pain, mean depressed mood levels of 17.9, and only 19.4% of the group expecting the intervention to help, although this entire group was also prepared to make at least small changes to aid in their rehabilitation. In summary, there were no statistically significant differences in baseline characteristics between the two groups.

Intervention Group in Comparison to Control Group

Subjects in the intervention group had a statistically significant increase in their self-perceived health status while decreasing their scores in average pain intensity, PDI, BDI scores, days in pain, and hours in pain in comparison to the control group. Review of the 95% CIs of the absolute difference and the resulting *P* values indicate that there were no statistically significant changes in prescription or nonprescription drug usage or work status at intervention completion (Table 2).

To determine if the results observed between the intervention group and the control group were due to active stage of change instead of randomized group allocation, the groups were stratified into the 2 categories of active stage of change and preparing to make small changes. One difference was noted based on this stratification (average pain; $P = 0.012$), but none of the other health outcomes exhibited any statistically significant difference based on differences of being actively engaged in change in comparison to preparing to make change.

Twenty subjects in the intervention group reported minor musculoskeletal pain as a side effect, and four subjects in the control group indicated stomach irritation reportedly due to drug intervention. Cointerventions were avoided in all subjects during the trial, except 2 patients in the intervention group that maintained chiropractic or massage treatments as needed (three and two treatments, respectively). Attendance adherence to the entire protocol was 90.56 ± 1.72% at intervention completion for those that completed the intervention with no one below 80% attendance adherence (protocol adherence was not formally measured). There were no other protocol deviations.

Upon program completion, the intervention patients were asked to evaluate which treatment parameters were believed to be effective from 1 to 10 with 0 being completely not effective and 10 being completely effective. In order of preference, the patients prioritized supervised group exercise sessions at a mean score of 7.89 ± 2.70, physical therapy advice 5.64 ± 3.72, rheumatologist advice and group education lecture 4.56 ± 3.83, psychologist group pain and stress management lectures 4.00 ± 3.59, massage therapy 3.75 ± 3.90, and the group dietary lecture at 3.06 ± 3.60.

Long-Term Changes in Intervention Group Alone

Follow-up at 15 months postintervention revealed that the intervention group maintained statistically significant changes in all of the health outcomes mentioned above (average pain intensity, PDI, BDI scores, days in pain, and hours in pain) except health status, which regressed back to original baseline levels. At 15 months, the variables of prescription drug use and nonprescription drug use demonstrated statistically significant lowering for the first time in the intervention group. No changes were found in work status (Table 3). Comparisons were not made to the control group.

In total, 51% of the intervention group self-reported that they continued on with their exercise program at least 3 times a week during the 15-month follow-up period. Those that continued on with their exercise program had higher health outcomes than those that did not in PDI scores ($P = 0.012$), BDI scores ($P = 0.047$), and nonprescription medication usage ($P = 0.009$). No differences were found in the other health outcomes based on differences in long-term exercise adherence.

Binary logistic regression was used to determine if any variable had an independent effect on the outcome of long-term change in PDI scores. Only the covariate of continued exercise adherence upon completion of the initial intervention was a factor in the final model (OR = 5.333; 95% CI 1.446–19.671). In other words, those that did not continue on with their exercise program were 5.3 times less likely to have long-term changes in their PDI scores (lowering of at least 15 points in a scale of 70 points). The variable of income status was determined to be a confounder but not an effect modifier and, as such, was controlled for in the final model. Once controlled, income levels above $40,000 had a positive effect on outcome (77% more likely to lower PDI scores greater than 15 points). There were no other statistically significant confounders or effect modifiers influencing the final regression model. The R^2 of the final model was 0.441, suggesting reasonable explanation of the proportion of variance in the outcome variable explained by the knowledge of the explanatory variables. The goodness-of-fit test result ($P = 0.803$) suggests that the final model is appropriate and that the predicted values are accurate representations of the observed values in an absolute sense. In other words, the final model is able to estimate the probability of the outcome variable (long term change in PDI scores). The results are presented in Table 4.

TABLE 1. Baseline Characteristics of Fibromyalgia Patients

Variable	Intervention	Control	*P*
Patients	43	36	
Age (y)–mean ± SD	49.70 ± 9.57	49.11 ± 13.38	0.821
Sex–female (%)	37/43 (86.0)	30/36 (83.3)	0.738
Marital status–married (%)	26/43 (60.5)	20/36 (55.6)	0.659
Family income (%)			0.212
0–$20,000	10/43 (23.3)	13/36 (36.1)	
$20,001–$40,000	17/43 (39.5)	8/36 (22.2)	
$40,001–$60,000	11/43 (25.6)	13/36 (36.1)	
Over $60,000	5/43 (11.6)	2/36 (5.6)	
Education (%)			0.952
University/college	19/43 (44.2)	15/36 (41.7)	
High school graduate	20/43 (46.5)	18/36 (50.0)	
Less than high school graduate	4/43 (9.3)	3/36 (8.3)	
Current self-reported health (1–5)–mean ± SD	3.60 ± 1.03	3.67 ± 0.89	0.778
Onset of pain in mos–mean ± SD	121.70 ± 128.36	120.64 ± 118.32	0.998
Primary pain concern (%)			0.953
Head/neck/shoulders/arms	26/43 (60.5)	22/36 (61.1)	
Back/legs	14/43 (39.6)	11/36 (38.9)	
Precipitating event like an accident–yes (%)	18/43 (41.9)	11/36 (30.6)	0.299
Average pain intensity in last month (1–10)–mean ± SD	7.14 ± 1.37	7.56 ± 1.38	0.185
Most pain intensity in last month (1–10)–mean ± SD	8.49 ± 1.24	8.81 ± 1.12	0.240
Lowest pain intensity in last month (1–10)–mean ± SD	4.19 ± 2.37	4.61 ± 2.35	0.428
Days in last month with pain–mean ± SD	28.86 ± 3.19	28.82 ± 4.45	0.461
Usual pain in hours without relief–mean ±SD	637.47 ± 207.72	600.08 ± 248.35	0.468
Self-reported symptoms (%)			
Fatigue–yes	40/43 (93.0)	34/36 (94.4)	0.796
Sleep deprivation–yes	42/43 (97.7)	34/36 (94.4)	0.454
Emotional problems–yes	28/43 (65.1)	23/36 (63.9)	0.910
Headaches–yes	33/43 (76.7)	28/36 (77.8)	0.913
Morning stiffness–yes	41/43 (95.3)	33/36 (91.7)	0.503
Depression–yes	25/43 (58.1)	22/36 (61.1)	0.789
Anxiety–yes	29/43 (67.4)	24/36 (66.7)	0.942
Frustration–yes	37/43 (86.0)	28/36 (77.8)	0.338
Number of nonprescription medications–mean ± SD	1.14 ± 0.35	1.11 ± 0.32	0.709
Number of prescription medications–mean ± SD	1.33 ± 0.47	1.28 ± 0.45	0.650
Currently employed–yes (%)	26/43 (60.5)	18/36 (50.0)	0.351
Current/previous employer–sympathetic to condition (%)	13/43 (30.2)	8/36 (22.2)	0.422
Current/previous employment–like job (%)	18/43 (41.9)	14/36 (38.9)	0.789
Expect intervention will help (%)	10/43 (23.3)	7/36 (19.4)	0.781
Current stage of change (%)			0.250
Not intending to make change (precontemplation)	0/43 (0.0)	0/36 (0.0)	
Contemplating change but not ready (contemplation)	0/43 (0.0)	0/36 (0.0)	
Prepared to make small changes (preparation)	14/43 (32.6)	16/36 (44.4)	
Actively engaged in change (action)	15/43 (34.9)	14/36 (38.9)	
Actively engaged in change for months (maintenance)	14/43 (32.6)	6/36 (16.7)	
Beck Depression Inventory–mean ± SD	18.23 ± 10.72	17.89 ± 10.03	0.884
Pain Disability Index–mean ± SD	33.63 ± 10.78	33.47 ± 7.89	0.943

TABLE 2. Reported Change in Health Outcomes at Intervention Completion

Variable	Intervention	Control	Absolute Difference Between Groups (95% CI)	*P*
No. subjects	43	36		
Change in health status	0.60 ± 0.12	−0.03 ± 0.11	0.63 (0.31–0.95)	0.000
Change in average pain intensity	1.02 ± 0.25	0.22 ± 0.20	0.80 (0.14–1.46)	0.019
Change in Pain Disability Index	8.70 ± 1.51	1.97 ± 1.56	6.73 (2.38–11.07)	0.003
Change in Beck Depression Inventory	7.74 ± 1.17	0.97 ± 0.75	6.77 (3.87–9.67)	0.000
Change in days in pain last mos	7.49 ± 1.58	1.17 ± 1.06	6.32 (2.36–10.28)	0.002
Change in hours in pain last mos	276.84 ± 50.47	27.53 ± 41.93	249.31 (115.48–383.14)	0.000
Change in prescription drugs	0.38 ± 0.42	0.21 ± 0.31	0.17 (−0.85–1.18)	0.743
Change in nonprescirption drugs	−0.81 ± 0.12	−0.69 ± 0.23	−0.12 (−0.77–0.53)	0.716
Change in work status (%)				0.193
No change	38/43 (88.4)	34/36 (94.4)		
Back to work	5/43 (11.6)	1/36 (2.8)		
Off work as result	0/43 (0.0)	1/36 (2.8)		

Plus-minus values are means ± standard error of the mean.

DISCUSSION

We found that low-cost multidisciplinary rehabilitation in a group setting and nonclinical environment was effective in increasing health status while reducing average pain intensity, pain-related disability, depressed mood, days in pain, and hours in pain in the short term. In the long term, all of these health outcomes retained their significance (except health status) including statistically significant lowering of nonprescription and prescription medication usage. There were no short- or long-term changes in work status. The results of binary logistic regression on the outcome of long-term change in PDI scores suggest that this outcome is influenced by long-term adherence to exercise and higher income status.

TABLE 3. Reported Additional Change in Health Outcomes at 15-Month Follow-up in Intervention Group

Variable	Absolute Difference Between Groups (95% CI)	*P*
No. subjects	43	
Change in health status	0.33 (−1.26–0.64)	0.042
Change in average pain intensity	−0.21 (−0.80–0.38)	0.479
Change in Pain Disability Index	−6.51 (−11.33–−1.69)	0.009
Change in Beck Depression Inventory	2.77 (−0.85–6.39)	0.130
Change in days in pain last mos	1.35 (−2.88–5.57)	0.523
Change in hours in pain last mos	−174.37 (−278.04–−70.71)	0.002
Change in prescription drugs	−0.51 (−0.86–−0.17)	0.005
Change in nonprescription drugs	−1.09 (−1.59–−0.60)	0.000
Change in work status (%)		—
No change	43/43 (100.0)	
Back to work	0/43 (0.0)	
Off work as result	0/43 (0.0)	

Changes reported in this table are the changes in the intervention group from intervention completion to 15-month follow-up with no comparison to the control group. Either the result is not significant, and no additional change is observed (average pain intensity, BDI, days in pain, work status), or the change is significant and the observed results have either regressed to baseline levels (health status) or progressed to a new significance level (PDI, hours in pain, drug usage).

TABLE 4. Independent Variables Associated With Long-Term Pain Disability Index Change

Dependent variable				
Pain Disability Index change				
Above 15-point improvement on scale = 0				
Below 15-point improvement on scale = 1				
Independent or explanatory variables	B	SE	*P*	Adjusted OR (95% CI)
Did not continue exercise program upon completion*	1.674	0.666	0.012	5.333 (1.446–19.671)
Income status above $40,000 per year†	−1.482	0.676	0.029	0.227 (0.060–0.856)
Final $R^2 = 0.441$				
Hosmer-Lemeshow test for goodness-of-fit $P = 0.803$				
The odds ratios presented above have been adjusted for all other covariates in the final model.				

Description of Reference Categories:
*Continued with exercise program after intervention completion = 0; did not continue with exercise program = 1.
†Income status below $40,000 = 0; income status above $40,000 = 1.

Previous high-quality randomized trials have determined that self-management education and exercise had positive effects on quality of life, self-efficacy, and the Fibromyalgia Impact Questionnaire[29]; group education plus cognitive intervention demonstrated improvements in pain coping and pain control[30]; behavioral intervention and education had improvements in depression, self-reported pain behavior, observed pain behavior, and myalgia scores[31]; and aerobic exercise had positive effects on pain distribution, point tenderness, work capacity, pain, energy, and global subjective improvement, whereas stress management had positive influences on point tenderness alone.[32]

The design, data collection, and analysis of the trial and the consistency of the current findings to other randomized trials with similar treatment parameters leads the authors to believe that the study has high internal validity. The study also appears to have high external validity, as the baseline characteristics of the study subjects are very similar to the baseline characteristics of previous population-based research and randomized trials. For example, the baseline characteristics are similar to previous population-based research in the areas of age, sex, education level, and depression and to the randomized trials mentioned above in age, sex, education level, depression, onset of pain, and employment status. Only one trial had an inconsistency in the area of high educational attainment.[30] As such, the study group is believed to be similar to patients with fibromyalgia across varying populations and similar to patients with fibromyalgia within other randomized trials. An external generalizability consideration, however, is that all of the intervention patients in the current study were in at least some positive stage of change.[24] If a patient is not willing to engage in their own rehabilitation, treatment outcomes are less likely.[25] Treatment success observed during the intervention was possibly due to this mental willingness to participate and change despite prior skepticism that the intervention would not work. The results of the study retain internal validity, as the control group was also in a positive stage of change. However, health outcome differences were not observed when stratifying the groups based on active stage of change and preparing to make change in comparison to randomized group allocation. Nevertheless, it is likely that the results of the study can only be generalized to patient populations that are willing to actively participate and change in comparison to others that are not willing to do so. As well, the results of the final regression model indicate that outcome is influenced by long-term adherence to exercise (a reasonable proxy for active stage of change).

The current study has other limitations to consider. First, the treatment patients were not blinded to intervention status, as this was not considered possible. It is possible that the intervention group responded differently in comparison to the control group as a result of the special attention and interest that they received, a phenomenon called the Hawthorne effect. Unfortunately, the authors did not include a control group that incorporated special attention and interest above and beyond standard medical care and, as such, cannot determine the independent effect of this variable. Also, all of the study subjects were volunteers. It is possible that intervention patients might have wanted to assist with favorable results and control patients might have wanted to demonstrate unfavorable results after years of failed primary care. This potential was minimized but not eliminated through the use of blinded measurements (subjects did not have access to their original scores or questionnaires). This does not change the fact, however, that the effectiveness of the intervention has not been tested in a primary care (nonresearch) setting. Additional trials need to be performed to determine which patient characteristics will enhance or hinder intervention effectiveness. Component analysis studies need to be done to determine the extent to which each component within the multidisciplinary intervention con-

tributes to health outcome. The optimal length of the intervention also needs to be established (the current length of the study was based on the average treatment duration in Saskatchewan, Canada). The cost effectiveness of the intervention also needs to be thoroughly reviewed. In the current intervention, the group nature and community setting of the protocol would have cost the patient approximately $300 Canadian for treatment staffing and YMCA membership fees. Finally, long-term exercise adherence was based on self-reporting. There is no way to confirm that the subjects actually performed their exercises, let alone performed them correctly. There is also no way of knowing if the patients actually performed their cognitive-behavior therapy at home or any of their other self-management techniques taught during the program.

Multidisciplinary rehabilitation is common in the treatment of fibromyalgia and chronic widespread pain across North America, but the effectiveness, let alone the cost effectiveness, of these expensive programs are unknown.[1] The underlying hypothesis is that chronic pain is a specific medical disorder requiring specific clinical intervention.[25] The current multidisciplinary rehabilitation program is general in nature (no single specific outcome like return to work or function in comparison to pain) and can be implemented for a few hundred Canadian dollars. Future studies need to address the cost-effectiveness of general self-management programs in comparison to more specific clinical programs with specific clinical or vocational goals. After all, fibromyalgia prevalence is associated with Western culture, female gender, older age, low-income status, low educational attainment, and depression. Perhaps these associations suggest that a greater percentage of patients would benefit from more simple and general management approaches that focus on exercise, education, lifestyle changes, and self-management. These low-cost, nonclinical alternatives would also enable patients to assist in the management of their own disorder.

In summary, our study provides evidence that short and long-term positive health related outcomes in this mostly unresponsive condition can be obtained with a low-cost, group multidisciplinary intervention in a community-based, nonclinical setting.

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