Research Submissions

Effectiveness of Multidisciplinary Intervention in the Treatment of Migraine: A Randomized Clinical Trial

Mark Lemstra, MSc; Brad Stewart, MD, FRCP(C); W. P. Olszynski, MD, PhD, FRCP(C)

Objective.—To test the effectiveness of a multidisciplinary management program for migraine treatment in a group, low cost, nonclinical setting.

Design.—A prospective, randomized, clinical trial.

Background.—Although numerous studies document the efficacy of pharmacological migraine management, it is unclear whether an effective long-term management approach exists.

Methods.—Eighty men and women were randomly assigned to 1 of 2 groups. The intervention group consisted of a neurologist and physical therapist intake and discharge, 18 group-supervised exercise therapy sessions, 2 group stress management and relaxation therapy lectures, 1 group dietary lecture, and 2 massage therapy sessions. The control group consisted of standard care with the patient's family physician. Outcome measures included self-perceived pain intensity, frequency, and duration; functional status; quality of life; health status; depression; prescription and nonprescription medication use; and work status. Outcomes were measured at the end of the 6-week intervention and at a 3-month follow-up.

Results.—Forty-one of 44 patients from the intervention group and all 36 patients from the control group completed the study. There were no statistically significant differences between the 2 groups before intervention. Intention to treat analysis revealed that the intervention group experienced statistically significant changes in self-perceived pain frequency ($P = .000$), pain intensity ($P = .001$), pain duration ($P = .000$), functional status ($P = .000$), quality of life ($P = .000$), health status ($P = .000$), pain related disability ($P = .000$), and depression ($P = .000$); these differences retained their significance at the 3-month follow-up. There were no statistically significant changes in medication use or work status.

Conclusions.—Positive health related outcomes in migraine can be obtained with a low cost, group, multidisciplinary intervention in a community based nonclinical setting.

Key words: migraine, multidisciplinary, pain, disability, depression, randomized clinical trial

(*Headache.* 2002;42:845-854)

Migraine is an ever-increasing concern in society. The prevalence of migraine is approximately 18% for women and 6% for men.[1] Effective long term management of patients with migraine is challenging because of the heterogeneity and complexity of the condition.[2] Although the evidence-based management of migraine is mostly pharmacological, many people with migraines no longer seek the help of a physician[3,4] despite significant pain, disability, and reduced quality of life.[4-7] In fact, half of patients with migraine stop seeking care for their headaches partly because they are dissatisfied with treatment.[2] In response, public health surveys indicate that people with migraines are among the most dissatisfied of all medical patients.[8] As such, other nonpharmacological options need to be developed to reach a wider range of pa-

From Saskatoon, Saskatchewan (Mr. Lemstra); the Department of Medicine, University of Alberta, Edmonton, Alberta (Dr. Stewart); and the College of Medicine, University of Saskatchewan, Saskatoon, Saskatchewan (Dr. Olszynski), Canada.

Address all correspondence to Dr. W. P. Olszynski, College of Medicine, University of Saskatchewan, 103 Hospital Drive, Saskatoon, SK S7N 0W8, Canada.

Accepted for publication July 6, 2002.

tients with varying individual concerns, responses, beliefs, and values.

The current management of patients with migraine includes attempting to prevent attacks by identifying and removing potential trigger factors individual to each patient; attempting to prevent attacks through relaxation therapy and stress management[9]; attempting to prevent recurring attacks with pharmacological intervention, including β-blockers, calcium channel blockers, antidepressants, and anticonvulsants[2]; and the treatment of acute attacks with simple analgesics, nonsteroidal anti-inflammatory drugs, and triptans.[10] Unfortunately, the high cost currently associated with medications, the potential for overuse, medical contraindications, medication intolerance, patient preference, and overall medication effectiveness compared with efficacy represent significant limitations to pharmacological management. As such, migraine presents an important yet elusive public health concern.

In response, we designed a prospective, randomized, clinical trial to test the effectiveness of multidisciplinary intervention in a group, low cost, nonclinical setting with standard medical care. The intervention prioritized a general management approach consisting of exercise, education, lifestyle change, and self-management. The primary outcomes were self-reported pain frequency, pain intensity, pain duration, functional status, quality of life, health status, pain related disability, depression, medication use, and work status. The methodology of the trial was based on the recommendations of the CONSORT statement.[11]

METHODS

Study Design and Subjects.—A trial project of 18 cases was initiated before the intervention to determine protocol effectiveness, compliance, safety, and the validity and reliability of the questionnaire. Upon completion, a letter was sent to every family physician within city limits asking them to refer patients to the research protocol. Eligible subjects required a referral from their physician indicating a diagnosis of migraine and safety to participate. Subjects were also required to have chronic migraine pain for at least 6 months and to meet the diagnostic criteria for migraine with or without aura in accordance with the International Headache Society.[12] The subjects also had to be 18 years of age or older in order to give written informed consent. Patients were excluded if their pain was of a benign nature. Patients were not excluded for any other comorbidity.

Eighty-four potential clients were referred, of which 4 clients declined to participate. Eighty men and women were randomly assigned to 1 of 2 groups. The intervention group consisted of a neurologist intake, physical therapist intake, 18 group-supervised exercise therapy sessions with an exercise therapist, 2 group lectures with a registered psychologist, 1 group lecture with a dietitian, 2 massage therapy sessions, and a neurologist and physical therapist discharge. The initial neurologist evaluation was intended to confirm the diagnosis, obtain a detailed history, and confirm appropriateness to participate. A management plan with the patient was also developed at this time to identify medication use, identify and remove potential trigger factors, promote long-term lifestyle changes, create realistic expectations, promote the importance of full participation, and communicate with the family physician. The physical therapist provided a detailed biomechanical evaluation, provided education on hurt versus harm, identified barriers to participation, and initiated an action plan to prevent dropout. The physical therapist did not provide neck mobilization or manipulation. The exercise therapist supervised the exercise therapy sessions, which included submaximal aerobic exercise, stretching, and light weight training, and monitored attendance and created a social nonintimidating environment for the patients. The psychologist provided 1 group lecture on relaxation training and another on behavioral modification and stress management. The group sessions were both lecture format and practical. The dietitian provided 1 group lecture on general dietary goals and explained how to substitute alternatives to potential dietary triggers. The massage therapist provided 2 individual sessions with the goal of relaxation and a means of reward after initial exercise sessions rather than any type of therapeutic benefit.

The waiting list control group consisted of standard medical care with the patient's family physician.

The control intervention included medical specialist referral (19%), referral to treatment (11%), medication (56%), further diagnostics (0%), education (0%), and nothing at all (14%).

The unit of randomization was individual, computer generated, and envelope concealed 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 and therapists before intervention. Therapists were blind as to which specific outcome variables were primarily under evaluation. The outcome assessor was blind to the intervention status. Additional management or treatment other than family physician was discouraged during the trial but was 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 held at a local YMCA to promote a social, nonclinical, nonintimidating environment. The primary components of the intervention were submaximal general exercise, education, lifestyle changes, and self-management. Active participation was maximized with supervised visits, telephone 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. The intervention team made attempts to develop a coordinated management plan that included the family physician, the patient, and, if requested, family members.

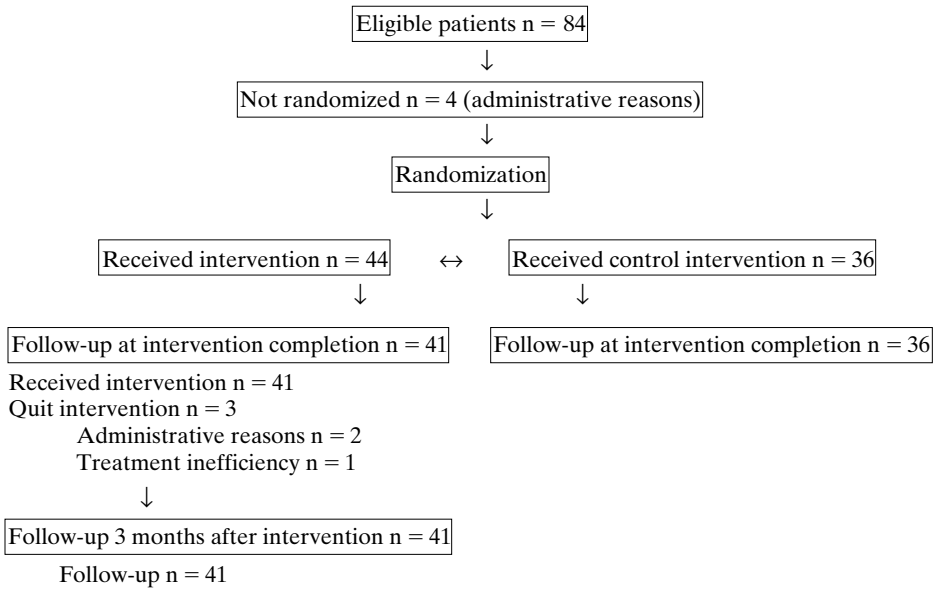
Outcome Measures.—Written questionnaires were completed at the time of randomization and at the end of the 6-week intervention. A telephone questionnaire was conducted 3 months after the completion of the intervention. Before and after blinded measurements were taken for the following: health status rated from 1 (excellent health) to 5 (poor health)[13]; average pain, most severe pain, and least pain in the last month rated from 0 (no pain) to 10 (pain as bad as it can be) (Visual Analogue Scale[14]); days in pain and hours in pain without relief in the last 30 days; prescription and nonprescription drug use in the last 30 days; impact of chronic migraine pain in everyday life, including family, recreation, social activity, occupation, sexual behavior, self-care, and life support activity (Pain Disability Index[15]); and 21 statements that best describe their feelings within the last 2 weeks (Beck Depression Inventory II[16]). Work status was evaluated before and after the intervention. After intervention only measurements were taken in self-perceived changes in pain frequency, pain intensity, pain duration, functional status, and quality of life. These outcomes were measured with a Visual Analogue Scale that included values from 100% worse to 100% improvement.

Statistical Analysis.—Chi-square 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 (β, 0.80; α, 0.05; D, 10; SD, 15). The intention to treat principle was used to compare the intervention and control groups. 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 chi-square test was used. Ninety-five percent confidence intervals were also built around the mean absolute difference between the 2 groups. Multivariate adjustment was not required because of the similarity of baseline characteristics between the intervention and control groups.

RESULTS

Participant Flow.—Forty-four subjects began the intervention group, and 36 subjects began the control group. Three subjects quit the intervention protocol before completion, citing lack of time, administrative reasons, and program ineffectiveness. In total, 41 subjects completed the 6-week intervention, and all 36 subjects completed the control (Table 1). 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. Three-month follow-up information

Table 1.—Progress Through Various Stages of the Randomized Trial



was collected on the intervention group after completion on October 31, 2001.

Characteristics of the Subjects.—The baseline demographic, clinical, psychological, and behavioral characteristics between the intervention group and the control group were similar (Table 2). The demographic characteristics of the intervention group were a mean age of 35.6 years, 72.7% women, 31.8% low income status, 63.6% high school education or less, and 72.7% employment rate. The clinical factors were low self-reported health (3.6 out of 5); 102.9 months of previous pain, including 20.2 days in the last month; and high average pain (7.3 out of 10). Psychologically, the mean depression levels were 16.1, suggesting marked depressed mood levels for the entire group. Behaviorally, 27.3% of the group expected the intervention to help, and 93.2% of the entire group was at least prepared to make small changes to aid in their rehabilitation.[16]

The demographic characteristics of the control group were a mean age of 33.2 years, 58.3% women, 41.7% low income status, 66.7% high school education or less, and 80.6% employment rate. The clinical factors included low self-reported health (3.7 out of 5); 101.7 months of previous pain, including 21.0 days in the last month; and high average pain (7.1 out of 10). Psychologically, the mean depression levels were 17.5, suggesting marked depressed mood levels for the entire group. Behaviorally, 36.1% of the group expected the intervention to help, and 91.6% of the entire group was at least prepared to make small changes to aid in their rehabilitation. In summary, no statistically significant differences were seen in baseline characteristics between the two groups.

Potential precipitating factors of migraines were reviewed for both groups. By far, the most frequently reported trigger factors were the variables of emotional stress and fatigue (Table 3).

Intervention Group Compared with Control Group.—Subjects in the intervention group reduced their self-perceived pain frequency by $33.64 \pm 5.29\%$, pain intensity by $19.55 \pm 5.61\%$, and pain duration by $28.75 \pm 5.17\%$ while increasing their functional status by $34.77 \pm 4.75\%$ and quality of life by $35.34 \pm 5.03\%$. In comparison, the control group increased their self-perceived pain frequency by $2.22 \pm 2.22\%$, pain intensity by $2.78 \pm 1.98\%$, and pain duration by $5.00 \pm 2.91\%$ while reducing their functional status by $0.56 \pm 2.03\%$ and quality of life by $1.94 \pm 1.94\%$. Review of the 95% confidence intervals of the absolute difference

Table 2.—Baseline Characteristics of Migraine Patients

Variable	Intervention	Control	*P* Value
Respondents	44	36	
Age in years*	35.59 ± 10.15	33.17 ± 13.21	.356
Gender, female (%)	32/44 (72.7)	21/36 (58.3)	.176
Marital status, married (%)	24/44 (54.5)	17/36 (47.2)	.514
Family income (%)			.817
0-$20,000	14/44 (31.8)	15/36 (41.7)	
$20,001-$40,000	19/44 (43.2)	14/36 (38.9)	
$40,001-$60,000	9/44 (20.5)	6/36 (16.7)	
Over $60,000	2/44 (4.5)	1/36 (2.8)	
Education (%)			.822
Some university or college	16/44 (36.3)	12/36 (33.3)	
High school graduate	25/44 (56.8)	23/36 (63.9)	
Less than high school graduation	3/44 (6.8)	1/36 (2.8)	
At least one parent has chronic headaches	26/44 (59.1)	21/36 (58.3)	.946
Current self-reported health (1-5)*	3.60 ± 1.03	3.67 ± 0.89	.795
Onset of pain, months*	102.91 ± 77.75	101.67 ± 128.35	.958
Precipitating event like an accident, yes (%)	6/44 (13.6)	6/36 (16.7)	.706
Average pain in last month (1-10)*	7.34 ± 1.87	7.14 ± 2.02	.644
Most pain in last month (1-10)*	9.05 ± 1.33	9.11 ± 1.35	.828
Lowest pain in last month (1-10)*	3.68 ± 3.24	3.03 ± 2.97	.354
Days in last month with pain*	20.20 ± 8.07	21.08 ± 8.33	.634
Usual pain in hours without relief*	162.27 ± 207.68	166.14 ± 229.45	.937
Self-reported symptoms (%)			
One side of head pain always/often, yes	30/44 (68.2)	21/36 (58.3)	.787
Pounding in head always/often, yes	32/44 (72.7)	27/36 (75.0)	.591
Nausea always/often, yes	23/44 (52.3)	16/36 (44.4)	.608
Vomiting always/often, yes	8/44 (18.2)	7/36 (19.5)	.718
Worse with activity always/often, yes	35/44 (79.5)	26/36 (72.2)	.752
Sensitive to light always/often, yes	34/44 (77.2)	31/36 (86.0)	.720
Sensitive to noise always/often, yes	33/44 (75.0)	29/36 (80.6)	.832
Number of nonprescription meds*	1.86 ± 0.95	2.00 ± 0.89	.515
Number of prescription meds*	2.55 ± 2.17	2.17 ± 2.09	.432
Currently employed, yes (%)	32/44 (72.7)	29/36 (80.6)	.413
Current/previous employer			
Sympathetic (%)	23/44 (52.3)	22/36 (61.1)	.428
Like job (%)	24/44 (54.5)	21/36 (58.3)	.734
Expect intervention will help (%)	12/44 (27.3)	13/36 (36.1)	.483
Current stage of change (%)			.875
Not intending to make changes	1/44 (2.3)	2/36 (5.6)	
Contemplating change but not ready	2/44 (4.5)	1/36 (2.8)	
Prepared to make small changes	14/44 (31.8)	9/36 (25.0)	
Actively engaged in change	17/44 (38.6)	16/36 (44.4)	
Actively engaged in change for months	10/44 (22.7)	8/36 (22.2)	
Beck Depression Inventory*	16.05 ± 10.47	17.53 ± 9.82	.519
Pain Disability Index*	32.95 ± 12.92	34.19 ± 16.06	.703

*Values are means ± SD.

Table 3.—Trigger Factors Associated with Migraines

Variable	Intervention	Control
Hormonal		
Menstruation	16/32 (50.0)	12/21 (57.1)
Birth control pills	5/32 (15.6)	4/21 (19.0)
Hormone replacement therapy	5/32 (15.6)	4/21 (19.0)
Environmental		
Bright light	28/44 (63.6)	28/36 (77.8)
Persistent loud noise	30/44 (68.2)	28/36 (77.8)
Weather changes	26/44 (59.1)	18/36 (50.0)
Strong odors	24/44 (54.5)	18/36 (50.0)
Allergies	15/44 (34.1)	15/36 (41.7)
Behavioral		
Skipping a meal	26/44 (59.1)	18/36 (50.0)
Sleeping more than usual	17/44 (38.6)	13/36 (36.1)
Sleeping less than usual	31/44 (70.5)	25/36 (69.4)
Emotional stress	37/44 (84.1)	32/36 (88.9)
Dietary		
Chocolate	19/44 (43.2)	12/36 (33.3)
Cheese	17/44 (38.6)	8/36 (22.2)
Cured meats	12/44 (27.3)	6/36 (16.7)
Caffeine	14/44 (31.8)	13/36 (36.1)
Alcohol	22/44 (50.0)	16/36 (44.4)
Aspartame	15/44 (34.1)	10/36 (27.8)

Values in parentheses are percents.

and the resulting probability values indicated that the intervention group, comparison with the control group, had a statistically significant influence on all of the health outcomes mentioned above (Table 4).

Subjects in the intervention group increased their self-perceived health status by $0.73 \pm 0.12\%$ while decreasing their blinded scores in average pain by 2.29 ± 0.39, most pain by 1.57 ± 0.35, least pain by 1.55 ± 0.38, days in pain by 9.50 ± 1.41 days, and hours in pain without relief by 95.86 ± 28.66 hours. Pain Disability Index scores reduced by 14.50 ± 2.13, and Beck Depression Inventory scores reduced by 9.77 ± 1.23. In comparison, subjects in the control group lowered their self-perceived health status by 0.05 ± 0.03 while reducing their blinded average pain scores by 0.15 ± 0.17, most pain scores by 0.03 ± 0.14, increasing least pain scores by 0.28 ± 0.30, and reducing days in pain by 1.31 ± 0.36 days and hours in pain without relief by 4.53 ± 3.05 hours. Pain Disability Index scores also reduced by 1.72 ± 0.96, and Beck Depression scores reduced by 1.17 ± 0.46. Review of the 95% confidence intervals of the absolute difference and the resulting probability values indicated that the intervention group, compared with the control group, had a statistically significant influence on the health outcomes of health status, average pain intensity, most pain intensity, least pain intensity, days in pain, hours in pain without relief, pain related disability, and depressed mood (Table 4). Although changes in prescription and nonprescription drug use were statistically significant by way of probability value, they were not significant after reviewing the 95% confidence intervals. Changes were also observed in work status, but these results were not statistically significant.

Additional follow-up at 3 months after intervention revealed that the intervention group maintained statistically significant changes in self-perceived frequency of pain ($P = .000$), intensity of pain ($P = .000$), duration of pain ($P = .000$), functional status ($P = .000$), quality of life ($P = .000$), average pain ($P = .000$), most pain ($P = .000$), least pain ($P = .000$), pain related disability ($P = .000$), and depressed mood ($P = .000$). No statistically significant differences were found for prescription or nonprescription drug use after reviewing both the probability values and the 95% confidence intervals (Table 5). The variables of health status, days in pain, hours in pain, and work status were not measured at the 3-month follow-up. In total, 59% of the intervention group continued with their exercise program at least 3 times a week during the follow-up period. Those who continued with their exercise program had higher health outcomes than those who did not (data not shown).

Upon program completion, the intervention patients were asked to evaluate from 1 to 10 (0, completely not effective; 10, completely effective) which treatment parameters were believed to be effective. In order of preference, the patients prioritized supervised group exercise sessions at a mean score of 7.80 ± 2.34, physical therapist advice 5.76 ± 3.31, neurologist advice and education 3.93 ± 3.34, psychologist group stress management and relaxation training lectures 3.71 ± 3.34, group dietary lecture 3.66 ± 3.29, and massage therapy sessions at 3.56 ± 3.15.

Eight subjects in the intervention group reported minor musculoskeletal pain and 2 reported medication intolerance, whereas 1 subject in the control group indicated a medication complication. Co-interventions

Table 4.—Reported Change in Health Outcomes at Intervention Completion

Variable	Intervention	Control	Absolute Difference Between Groups (95% CI)	*P* Value
Number of Subjects	44	36		
After intervention only				
Change in pain frequency	33.64 ± 5.29	−2.22 ± 2.22	35.86 (23.53-48.19)	.000
Change in pain intensity	19.55 ± 5.61	−2.78 ± 1.98	22.32 (9.46-35.19)	.001
Change in pain duration	28.75 ± 5.17	−5.00 ± 2.91	33.75 (21.21-46.29)	.000
Change in functional status	34.77 ± 4.75	−0.56 ± 2.03	35.33 (24.25-46.41)	.000
Change in quality of life	35.34 ± 5.03	−1.94 ± 1.94	37.29 (25.66-48.91)	.000
Before and after intervention				
Change in health status	0.73 ± 0.12	−0.05 ± 0.03	0.78 (0.50-1.06)	.000
Change in average pain	2.29 ± 0.39	0.15 ± 0.17	2.13 (1.19-3.08)	.000
Change in most pain	1.57 ± 0.35	0.03 ± 0.14	1.54 (0.73-2.35)	.000
Change in least pain	1.55 ± 0.38	−0.28 ± 0.30	1.82 (0.83-2.82)	.000
Change in days in pain	9.50 ± 1.41	1.31 ± 0.36	8.19 (5.01-11.37)	.000
Change in hours in pain	95.86 ± 28.66	4.53 ± 3.05	91.34 (27.95-154.72)	.005
Change in prescription drugs	1.18 ± 0.24	0.22 ± 0.11	0.96 (0.38-1.53)	.001
Change in nonprescription drugs	1.06 ± 0.22	0.25 ± 0.12	0.81 (0.26-1.37)	.005
Change in Pain Disability Index	14.50 ± 2.13	1.72 ± 0.96	12.78 (7.78-17.77)	.000
Change in Beck Depression Inventory	9.77 ± 1.23	1.17 ± 0.46	8.61 (5.77-11.44)	.000
Change in work status (%)				.063
No change	40/44 (90.9)	36/36 (100.0)		
Back to work	4/44 (9.1)	0/36 (0.0)		
Off work	0/44 (0.0)	0/36 (0.0)		

were avoided in all subjects during the trial except 2 clients in the intervention group who maintained chiropractic or massage treatments as needed (4 and 2 treatments, respectively). Attendance adherence to the entire protocol was 87.58 ± 11.98% for those who completed the intervention. There were no other protocol deviations. There were no attempts to statistically adjust for baseline differences because there were none.

COMMENTS

We found that a potentially low cost, group, multidisciplinary intervention occurring in a nonclinical environment was effective in reducing self-perceived pain frequency, pain intensity, pain duration, average pain intensity, most pain intensity, low pain intensity, pain related disability, and depression and in increasing self-perceived functional status, quality of life, and health status. There were no overall statistically significant changes in medication use or work status between the 2 groups.

Ten previous randomized trials determined that relaxation training yielded a mean improvement of 32% in headache index or frequency from pre- to posttreatment.[9] Cognitive behavior therapy, or stress management, resulted in an average improvement of 49% in headache activity in 7 randomized trials reviewed.[9] One randomized trial for normal populations found benefit to combining physical therapy with relaxation training, although physical therapy alone was not found to be effective in reducing migraine.[17] No other randomized trials evaluating the effectiveness of multidisciplinary intervention were found. As well, there were no randomized trials found to test the effectiveness of exercise therapy alone despite its wide consensus as a management technique.[18-20] Although the identification and removal of trigger factors is considered important for successful migraine management, no randomized clinical trials were found to specifically test this theory.

The design, data collection, and analysis of the trial and the consistency of the current findings to

Table 5.—Reported Change in Health Outcomes at 3-Month Follow-Up

Variable	Intervention	Control	Absolute Difference Between Groups (95% CI)	*P* Value
Number of subjects	44	36		
After intervention only				
Change in pain frequency	56.93 ± 9.13	−2.22 ± 2.22	59.15 (38.65-79.66)	.000
Change in pain intensity	38.18 ± 8.54	−2.78 ± 1.98	40.96 (21.80-60.12)	.000
Change in pain duration	47.16 ± 8.33	−5.00 ± 2.91	52.16 (33.07-71.25)	.000
Change in functional status	51.59 ± 7.71	−0.56 ± 2.03	52.15 (34.78-69.51)	.000
Change in quality of life	57.05 ± 8.17	−1.94 ± 1.94	58.99 (40.66-77.32)	.000
Before and after intervention				
Change in average pain	3.25 ± 0.49	0.15 ± 0.17	3.11 (2.16-4.07)	.000
Change in most pain	2.53 ± 0.44	0.03 ± 0.14	2.53 (1.52-3.49)	.000
Change in least pain	2.47 ± 0.47	−0.28 ± 0.30	2.74 (1.58-3.91)	.000
Change in prescription drugs	1.20 ± 0.24	0.22 ± 0.11	0.98 (0.42-1.55)	.001
Change in nonprescription drugs	0.84 ± 0.20	0.25 ± 0.12	0.67 (0.20-1.14)	.006
Change in Pain Disability Index	18.80 ± 2.23	1.72 ± 0.96	17.07 (11.87-22.28)	.000
Change in Beck Depression Inventory	10.61 ± 1.25	1.17 ± 0.46	9.45 (6.56-12.33)	.000

other randomized trials with nonpharmacological management lead us to believe that the study has high internal validity. The study also appears to have high external validity because the baseline characteristics of the study subjects are very similar to the baseline characteristics of previous population based research in the areas of age, gender, income status, and depression.[21-24] As well, the study subjects reported similar trigger factors and symptoms in similar percentages compared with other published research.[25–28] An external generalizability consideration is that most of the intervention patients in the current study were in at least some positive stage of change. If a patient is not willing to actively engage in their own rehabilitation, treatment outcomes are less likely. 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 because the control group was also in a positive stage of change. Nevertheless, it is likely that the results of the study can only be generalized to patient populations willing to actively participate and change.

The current study has other limitations to consider. First, the treatment patients were not blinded to intervention status because this was not considered to be possible. It is possible that the intervention group responded differently compared with the control group as a result of the special attention and interest they received, a phenomenon called the Hawthorne effect. As well, all 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. This does not change the fact, however, that the intervention has not been tested in a primary care 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 contributes to health outcome. The optimal length of the intervention also needs to be established. 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 $250 Canadian for treatment staffing and YMCA membership fees.

The current management of patients with migraines is mostly pharmacological. However, although many medical interventions have been proven to be efficacious, there are many limitations to the long-term effectiveness of these approaches. After all, migraine prevalence is associated with Western culture, female gender, middle age, low income status, depression, anxiety, emotional stress, and fatigue,[21-26,29-33] Perhaps these associations suggest that a greater percentage of patients would benefit from more simple and general management approaches[34] 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-term, positive, health related outcomes in this elusive condition can be obtained with a low cost, group, multidisciplinary intervention in a community based nonclinical setting. Additional trials need to be developed to determine the long-term effectiveness and cost effectiveness of general nonpharmacological management approaches.

Acknowledgment: We sincerely thank Brenna Bath, Michelle Wilm, Jo Nanson, Matt Regier, Lenore Pollock, and Nicole Lemstra for their hard work and dedication to this project.

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