No Clinical Effect of Back Schools in an HMO
A Randomized Prospective Trial

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In a prospective trial, 222 adults with low-back pain of at least 2 weeks' duration in a Health Maintenance Organization (HMO) were randomly assigned to usual care (UC), a 4-hour back school psychoeducational session (LBS), or the same back school plus a 1-year "compliance package" program designed to encourage appropriate self-management for back pain (CP). Sixty-four percent of LBS and CP subjects attended their back school sessions. Follow-up measurement of pain level (using the Visual Analogue Scale), functional status (using the Sickness Impact Profile), and various other indicators of health status showed no measurable effect of either treatment condition (LBS or CP) compared with UC at 3, 6, 12, and 18 months after entry into the study. Initial disability resolved by 3 months in most patients, and a minority of subjects (10–15%) showed residual or recurrent functional impairment 1 year after entry. Health care utilization tended to be slightly higher after intervention in the CP group. With or without follow-up encouragement, back school instructions given in a single 4-hour session had no measurable impact on the comfort or functional status of the majority of patients with new onset back pain in this HMO. [Key words: low-back pain, back school, prospective trial, negative outcome]

LOW BACK PAIN (LBP) is a common and expensive problem in modern health care. It afflicts over two out of every three adults at some time in their lives.[1,13,27] and is the most frequent cause of activity limitation in the United States for people under 45 years of age.[12] Low-back pain accounts for more work days lost than any other single symptom in the United States and is the major reason for compensation for work-related disability.[6]

Despite its frequency, LBP remains a condition without well-established therapeutic options. A recent review of clinical trials of treatments for LBP found a dearth of well-controlled studies, and equivocal results among the few studies with sound, prospective designs.[5] Promising modalities include psychoeducational techniques, such as the "Back Schools" pioneered in Sweden,[3,7,9] specific forms of exercise,[14] and, for severe cases, antidepressant medication,[23] but no therapeutic strategy has been shown beyond reasonable doubt to have advantages over the simple natural history of back pain for the average victim.[6]

Back schools, instructing LBP sufferers in exercises, ergonomic techniques, and the psychologic aspects of LBP, have been studied with some enthusiasm in Sweden, where initial investigations suggested that Back School attendance could accelerate the short-term resolution of symptoms.[3,9] Follow-up studies, however, indicate that longer term relapse rates remain unaffected by the Back School program.[15,16] The failure of Back Schools to affect relapse rates at 1 year is sometimes attributed to poor long-term patient compliance. In the United States, Back School programs have nonetheless become relatively common for use in conjunction with standard medical treatment.[7,10,17]

At the Harvard Community Health Plan (HCHP), the largest Health Maintenance Organization (HMO) in New England, LBP is one of the most common symptomatic reasons for a visit, and accounts for a large proportion of referrals for specialty orthopaedic care. To explore the potential role of Back Schools in such a setting, a randomized clinical trial for LBP victims was conducted at HCHP. The previously demonstrated lack of effect of Back Schools on relapse rates led to the inclusion of a specially modified program, supplementing a standard form of Back School with a 1-year program specifically designed to enhance patient compliance with exercises, ergonomic techniques, and other psychoeducational advice.

METHODS

Subjects. Using the automated medical record system at HCHP, adults with low-back pain or a related diagnosis were identified at the time of their first symptomatic encounter (telephone or visit) with an internist or nurse practitioner in the HMO. Adults aged 21 to 55 years of age, without serious comorbidity and without a prior history of back surgery, were initially eligible for the study. After a 2-week waiting period, subjects were contacted by telephone and screened with the following additional eligibility criteria: pain of at least 2 weeks' duration sufficient to impair normal work or activities, pain of a maximum of 6 months' duration, no prior episode of back pain within the previous year, and no known primary illness causing the back pain (such as osteomyelitis, metastic cancer, or osteoporosis). No attempt was made necessarily to exclude subjects with herniation of an intervertebral disc, but subjects were excluded if their pain characteristically extended below the level of the knee, suggesting nerve root compression or severe disc herniation.

Qualifying subjects were invited to participate in a randomized trial of educational methods for management of LBP. Those who agreed were mailed an initial battery of assessment tests, described below, and, after return of the materials, were assigned randomly to one of three experimental groups. Additional batteries of tests were mailed to subjects at 3 months, 6 months, 12 months, and 18 months after enrollment, and a final, detailed telephone "debriefing" was also done at 18 months. For each test battery mailed, subjects were pain a $10 honorarium.

Intervention. Subjects were randomly assigned to one of the following three conditions:

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Usual Care (UC). After enrollment, UC subjects were sent a single short phamphlet on LBP, and were thereafter contacted by the study only to assure completion of each test battery.

Low-Back School (LBS). After enrollment, LBS subjects were invited to attend a single, 4-hour session of instruction about LBP, taught at the HMO by a specially trained orthopaedic nurse practitioner and a physical therapist. In a pilot phase of the study, the initial plan of four successive 2-hour sessions for the Back School met with such poor attendance that a newly designed single 4-hour session was substituted as a more practical and easily attended psychoeducational intervention. Low-back school subjects left the session with an audiotape cassette of additional instruction and reinforcement of LBS content. Subjects assigned to the LBS condition who failed to attend an actual LBS session also were sent the tape with an instruction sheet urging that they listen to and learn the materials, which dealt with anatomy, pathophysiology, ergonomics, exercise, natural history, and psychologic issues in back pain.

Compliance Package (CP). Compliance package subjects received the same Back School intervention as the LBS subjects, but, in addition, received ongoing instruction and reinforcement by telephone and mail from study personnel for 12 months following enrollment. This follow-up package included a monthly newsletter ("The Spinal Column"), monthly telephone calls of support and encouragement from a study staff member, and additional special contacts such as birthday cards and other signs of interest from the study.

None of the study conditions involved contact with physicians in the HMO, except for an initial telephone call at enrollment to primary care doctors assuring that there were no specific contraindications to participation.

Dependent Variables. Throughout the study period, data of three types were collected on each study subject who agreed initially to participate.

Measures of Pain. At enrollment, 3 months, 6 months, 12 months, and 18 months, all subjects were asked to complete the McGill Pain Questionnaire[18] with respect to their back pain, and to mark a 10 cm Visual Analogue Scale for Pain (VAS)[11,19] ranging from no pain to severe pain. (The McGill instrument proved, in the end, too insensitive to pain in the range experienced by our subjects, and so the VAS became the primary pain measure for study of treatment effects in this study.)

Measures of Function. At each test battery, all subjects were asked to complete the 136-item self-administered form on the Sickness Impact Profile (SIP),[2,8,24] with specific reference to their back pain, and, in addition, to state the number of days in the previous 2 weeks during which back pain had forced them to spend any time in bed (Bed-days), out of work (Work-days), or to cut down on usual activities (Cut-days). The latter three questions used the phrasing of the Health Interview Survey of the National Center for Health Statistics.[22] In addition, the enrollment and 12-month batteries included the 90-item Symptom Checklist (SCL-90)[5] to assess psychologic status beyond that measured by the SIP.

Measures of Health Care Utilization. Using the computerized medical report at HCHP, the utilization of health care within the HMO was assessed for each subject for up to 12 months prior to enrollment in the study and for the 12-month period beginning at enrollment. For each period, annualized rates of use were calculated for the following six utilization variables:

1) Number of scheduled visits to primary care;

2) Number of unscheduled (walk-in, after-hours, and emergency care) visits;

3) Number of visits to an orthopaedic department;

4) Number of X-ray studies of any portion of the spine or lower back;

5) Number of visits of any type for back pain;

6) Number of visits to a mental health department or therapist.

Since the computerized record did not routinely contain information on health care utilization outside the HMO (although such utilization is thought to be less than 5% of total care), subjects were also asked in each enrollment battery about such out-of-plan utilization, including use of chiropractic (which is not offered by the HMO), osteopathy, acupuncture, and other nonphysician modalities of care. In addition, subjects were asked about their use of prescription drugs for the relief of back pain.

Data Analysis. All data were stored and analyzed on the VAX and IBM mainframe computers of the Health Sciences Computing Facility at the Harvard School of Public Health. Generally, the Statistical Analysis System (SAS) computing package was employed, although occasional log linear analyses were also done using other software. Treatment effects were explored primarily using analysis of covariance (ANCOVA) and related regression techniques, using each subject's age, gender, and enrollment (or pre-enrollment) level of pain, disability, or medical utilization as covariates. Where distributional considerations warranted, nonparametric techniques were used as well, examining, for example, whether the proportions of subjects free of pain at 12 months differed among the groups. All major analyses were performed by groups as assigned to treatment, and stratified analyses also were done for those subjects whose VAS scores at enrollment were above the lowest tertile.

RESULTS

Over the 8-month period during which enrollment occurred for this study, 247 patients met the initial eligibility criteria and stated that they were willing to participate. These patients all were mailed the enrollment history. Completed batteries were received from 222 subjects (90% of those agreeing), who were randomized to the three intervention conditions throughout the enrollment period (74 to UC, 72 to LBS, and 76 to CP). These 222 subjects constituted the base population for the follow-up batteries. Completed batteries were received from 82% of these 222 subjects

Table 1. Comparison of Groups at Enrollment

Variable	Group		
	Usual care ($n = 74$)	Low-back school ($n = 72$)	Compliance package ($n = 76$)
Mean age (years)	34.1	35.3	32.5
Women (%)	54	67	59
Smokers (%)	31	36	30
Mean educational level (ordinal scale)	3.8	3.8	3.9
VAS score ≥ 2 at enrollment (%)	59	72	67
Scores at enrollment			
VAS	2.6	2.8	2.9
Work days lost in prior 2 weeks	2.8	3.1	2.5
SIP—global	8.8	6.4	6.3
SIP—psychosocial	10.2*	6.2*	5.7*
SIP—physical	5.1	3.7	3.7
SCL-90 global	58	56	54

VAS = Visual Analogue Scale for Pain; SIP = Sickness Impact Profile; SCL-90 = 90-item Symptom Checklist.

Table 2. Outcomes on Pain Measures

Measure	Enrollment			3 mos			6 mos			12 mos			18 mos		
	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP
For all subjects															
N	74	72	76	64	55	64	65	59	60	69	66	70	66	60	69
Percent with any back pain	93	92	92	43	47	41	47	36	35	39	59	54	43	48	60
Mean VAS score	2.6	2.8	2.9	1.7	1.2	1.3	1.2	1.7	2.0	1.2	1.6	1.5	1.4	1.0	1.1
(SE)	(0.26)	(0.26)	(0.26)	(0.26)	(0.21)	(0.19)	(0.22)	(0.27)	(0.32)	(0.26)	(0.28)	(0.25)	(0.40)	(0.24)	(.24)
For subjects with enrollment VAS > 2															
N	44	52	48	37	41	42	37	42	37	39	50	46	20	27	35
Percent with any back pain	100	100	100	73	63	70	68	71	80	46*	70*	67*	45	56	74
Mean VAS score	3.9	3.6	4.1	2.4	1.5	1.6	1.8	2.0	2.5	1.4	1.9	1.9	1.4	1.2	1.4
(SE)	(0.29)	(0.27)	(0.27)	(0.38)	(0.25)	(0.25)	(0.33)	(0.34)	(0.41)	(0.37)	(0.33)	(0.35)	(0.48)	(0.28)	(0.30)

UC = usual care; LBS = low-back school; CP = back school plus compliance package; VAS = Visual Analogue Scale.
*$\chi^2 = 6.09$; 2 *df*; $P < 0.05$. Few significant differences are present. At 12 months, the Usual Care group is less likely to report pain than the LBS or CP groups among subjects with initial VAS scores of 2 or more.

Table 3. Functional Status Outcomes

Measure	Enrollment			3 mos			6 mos			12 mos			18 mos		
	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP	UC	LBS	CP
For all subjects															
Work days lost (% > 0)	43	51	42	32	27	19	22	14	32	20	19	20	14	19	19
Bed days (% > 0)	64	61	67	32	36	36	25	30	39	22	23	28	16	20	28
Drugs (% > 0)	76	65	76	60	44	35	44	48	48	33	36	32	22	33	33
SIP global (mean)	8.8	6.4	6.3	4.7	3.5	2.6	3.3	3.3	3.8	3.7	3.8	2.4	2.6	2.5	1.8
(SE)	(1.1)	(0.7)	(0.7)	(0.8)	(0.8)	(0.4)	(0.6)	(0.7)	(0.6)	(0.8)	(0.7)	(0.5)	(0.8)	(0.9)	(0.4)
SIP psychosocial (mean)	10.2	6.2	5.7	5.4	4.6	2.1	3.9	3.6	3.5	4.9	4.0	2.3	2.9	2.6	1.4
(SE)	(1.6)	(1.0)	(0.8)	(1.0)	(1.5)	(0.5)	(0.9)	(1.1)	(0.7)	(1.2)	(0.9)	(0.4)	(1.0)	(1.0)	(0.4)
SIP physical (mean)	5.1	3.7	3.7	2.2	1.4	1.3	1.3	1.5	2.3	1.4	3.8	1.1	1.0	1.2	0.8
(SE)	(0.9)	(0.6)	(0.6)	(0.6)	(0.4)	(0.3)	(0.4)	(0.5)	(0.5)	(0.6)	(0.5)	(0.4)	(0.5)	(0.7)	(0.3)
For subjects with enrollment VAS > 2															
Work days lost (% > 0)	61	59	49	41	29	21	30	12	36	25	21	17	20	20	16
Bed days (% > 0)	81	67	80	43	44	48	35	30	47	27	24	30	15	25	33
Drugs (% > 0)	82	75	82	76	51	45	51	52	58	33	41	41	25	38	39
SIP global (mean)	11.5	6.5	8.0	6.2	3.1	3.2	4.1	3.1	4.7	4.7	3.7	3.0	3.4	2.4	2.3
(SE)	(1.7)	(0.8)	(0.9)	(1.2)	(0.7)	(0.6)	(0.9)	(0.7)	(0.9)	(1.3)	(0.8)	(0.6)	(1.4)	(1.1)	(0.5)
SIP psychosocial (mean)	12.0	5.6	7.3	6.4	3.4	2.7	4.6	2.6	4.4	6.2	3.6	3.0	3.9	2.1	1.9
(SE)	(2.3)	(1.0)	(1.1)	(1.5)	(0.9)	(0.8)	(1.3)	(0.7)	(1.0)	(2.0)	(1.0)	(0.6)	(1.8)	(1.1)	(0.5)
SIP physical (mean)	7.6	4.1	4.8	3.4	1.6	1.4	1.8	1.7	2.8	1.9	1.6	1.3	1.3	1.3	1.1
(SE)	(1.4)	(0.7)	(0.8)	(1.0)	(0.5)	(0.3)	(0.6)	(0.7)	(0.7)	(1.0)	(0.5)	(0.4)	(0.8)	(0.8)	(0.5)

UC = usual care; LBS = back school; CP = back school plus 1-year compliance package; SIP = Sickness Impact Profile; VAS = Visual Analogue Scale for Pain.
Except for unfavorable SIP psychosocial scores in the UC group at enrollment, no significant differences in disability are seen. "Work Days Lost" refers to back-related days lost in the 2 weeks before assessment; "Bed Days" refers to any portion of a day spent in bed because of back pain in the 2 weeks. "Drugs" refers to any medication taken for back pain in the 2 weeks.

at 3 months, 83% at 6 months, 92% at 12 months, and 89% at 18 months. The three groups did not differ in follow-up rates.

Table 1 shows some pertinent characteristics of the three groups at enrollment. The only significant difference that randomization failed to prevent was on the SIP Psychosocial Disability (PSS) subscore, on which the UC group scored marginally higher (10.2%) than the LBS and CP groups (6.2% and 5.7%, respectively; chi square = 5.16; $P = 0.08$ by Kruskal-Wallis test). Because of this difference, special attention was given to both stratification and covariance analysis of treatment effects on the SIP, as described in more detail below. As Table 1 shows, there was a slight predominance of women in this sample (60%), and only two-thirds of the sample were actively in pain at the time of completion of the enrollment test battery.

Of the 72 subjects invited to attend the instructional session in the LBS group, 41 (57%) did in fact attend. In the CP group, 53 of 76 subjects (70%) attended the session. Attenders did not differ significantly from nonattenders in initial levels of pain or function.

RESULTS

Measures of Pain

Two primary pain measures were used to assess treatment effects, as shown in Table 2: the proportion of subjects reporting any back pain at all at each assessment, and the average pain level reported on the VAS. For the groups as a whole, fewer than half reported any pain by the 3-month follow-up battery, and that proportion remained relatively stable throughout the 18-month follow-up period. Subjects with higher levels of initial pain (VAS of 2 cm or greater) were more likely to report pain throughout the follow-up period. No significant differences among the three treatment groups were evident on either pain measure, except for a slightly decreased probability of pain at 12 months in the UC group. Of UC subjects with initial VAS scores of 2.0 or more, 54% were free of pain at 12 months, compared with 30% and 33% of the LBS and CP groups, respectively (chi square = 6.09; $df = 2$; $P = 0.048$). Despite an apparent difference at 3 months in VAS scores between the UC group and the other two groups among subjects with initial VAS scores of 2.0 or more, analysis of covariance, using initial VAS score as a covariate, failed to reveal any effect of treatment group at any follow-up assessment.

When those who attended the Back School sessions in the LBS and CP conditions were compared with the entire UC group, negative correlations were found between treatment and pain status at 12 months. For example, at 12 months, 39% of UC subjects reported some back pain, compared with 68% of LBS attenders and 55% of CP attenders (chi square = 8.22; $df = 2$; $P = 0.016$). This comparison is, of course, confounded by selection biases, since one cannot know who among the UC subjects would have attended Back School sessions if available to them.

Measures of Functional Status

In its self-administered form, the SIP appeared highly acceptable to subjects, with response rates approaching 90% despite the instrument's length. Table 3 shows the pattern of major SIP scores (Global, Psychosocial, and Physical) for the three treatment groups. (On the SIP, any scale score can be interpreted as the percentage of the maximum achievable disability on that subscale that a given subject reports.) Clear norms for comparison of SIP scores across disease states are not yet available. The average initial major scores in the range of 5 to 10% are somewhat lower than those reported in at least one previous study on patients referred for back pain to a chronic pain treatment program.[8]

Analysis of covariance, with initial scores as covariates, failed to reveal evidence of treatment effects. Scores fell for each group during the 3 months following enrollment, with the UC group scores remaining slightly higher than the LBS and CP scores on the Psychosocial Dimension, as was the case at entry. A separate analysis (not shown) was done to determine to proportion of each group with SIP scores of five or greater at each assessment. There were no differences among groups in the global SIP score at any time. On the Psychosocial scale score, the UC group had a higher proportion of members scoring five or more at enrollment (UC = 52%, LBS = 37%, CP = 35%, chi square = 5.68, $P = 0.06$) and at 3 months (UC = 36%, LBS = 26%, CP = 14%, chi square = 8.13, $P = 0.02$). On subscales of the psychosocial dimension there were occasional associations between scores and membership in the CP treatment group, but multiple comparisons using the SIP's 12 subscales over four follow-up assessments render such detailed statistical dragnets potentially misleading.

Additional analysis of functional status, comparing groups on disability days (Bed-days, Work-days, and Cut-days), and on the proportion taking drugs or staying in bed as reported by patients,

Table 4. Mean Sickness Impact Profile Scores at Enrollment and 12 Months Later

	Usual care		*Low-back school*		*Compliance program*	
SIP dimension	*Enrollment*	*12 mos*	*Enrollment*	*12 mos*	*Enrollment*	*12 mos*
Global	8.8	3.7	6.4	3.8	6.3	2.5
Physical	5.1	1.4	3.8	3.8	3.7	1.1
Ambulation	4.3	1.3	4.5	2.4	3.4	1.5
Body care	4.3	1.3	3.0	1.3	3.1	1.1
Mobility	8.1	2.1	5.1	2.2	5.4	0.9
Psychosocial	10.2	4.9	6.2	4.0	5.7	2.3
Emotional behavior	10.4	5.2	7.8	5.5	7.6	3.2
Social interaction	12.2	5.3	8.9	4.7	7.4	2.7
Alertness	11.2	6.3	4.1	4.0	4.9	1.5
Communication	4.9	2.4	1.7	1.6	1.6	1.4
Other						
Sleep and rest	14.4	7.4	13.2	9.1	10.3	6.6
Work	8.9	3.3	8.3	5.1	9.0	3.0
Eating	1.3	0.5	1.5	0.9	1.4	0.4
Home management	14.9	5.4	12.1	7.4	11.5	4.3
Recreation	19.9	9.0	14.7	7.2	19.1	8.1

After adjustment for enrollment level scores, no significant effects of treatment group are found. (The SIP score on any subscale represents the percentage of the maximum attainable score on that scale that is achieved by the subject.)

Table 5. Medical Care Utilization

Type of utilization	Percentage of subjects using any care			Rate of use—visits per year (SE)		
	UC	LBS	CP	UC	LBS	CP
(N=)	(73)	(72)	(76)	(73)	(72)	(76)
Scheduled visits						
Pre-intervention	88	81	86	3.51 (.35)	3.10 (.33)	4.30 (.60)
Post-intervention	86	82	89	4.39 (.49)	4.32 (.51)	6.08* (.83)
Unscheduled visits						
Pre-intervention	64	71	72	1.83 (.31)	1.85 (.27)	1.60 (.18)
Post-intervention	51	62	58	1.18 (.22)	1.24 (.19)	1.35 (.23)
Orthopaedic visits						
Pre-intervention	7	4	11	0.13 (.07)	0.06 (.03)	0.13 (.05)
Post-intervention	18	15	17	0.43 (.13)	0.30 (.09)	0.40 (.13)
Back X-rays						
Pre-intervention	21	11	21	0.23 (.06)	0.13 (.05)	0.28 (.09)
Post-intervention	5	10	11	0.05 (.03)	0.12 (.04)	0.13 (.05)
Visits for back pain						
Pre-intervention	71	76	86	1.54 (.21)	1.45 (.20)	1.36 (.12)
Post-intervention	38	38	42	1.03 (.22)	1.13 (.30)	1.62 (.38)
Mental Health Visits						
Pre-intervention	18	8	15	0.97 (.38)	0.34 (.15)	0.98 (.38)
Post-intervention	16	8	17	0.55 (.19)	0.86 (.49)	1.04 (.39)

*CP Group differs from others; F = 2.59; $P = 0.08$.

also failed to reveal statistically significant effects of treatment group. At 12 months, for example, 33% of the UC subjects stated that they were using some medication for back pain, compared with 36% of the LBS group and 32% of the CP group. Where trends existed, results tended to favor the UC group, despite its initially higher SIP values.

Table 4 displays SIP scores in more detail by group at enrollment and 12-month assessments. Despite the multiple comparisons involved, statistically significant effects of treatment group were not present using either logistic regression (with the enrollment scale score as a covariate and presence or absence of any positive SIP response as the dependent variable) or analysis of covariance on the SIP scores or their log transformations. Occasionally, membership in the CP group approached statistical significance as a predictor or lower scores on the Psychosocial dimension and its subscales, but the effects were slight and inconsistent.

Medical Utilization

Rates of use of health care, as measured by the six variables defined above, were highly skewed, and comparisons of means rates among groups may be misleading. Table 5 shows these rates by group annualized for the period prior to enrollment in the study and for the 12 months subsequent to enrollment. The table displays both the proportion of group members using any care in the stated category, and the annualized rate of use in visits per year. Only one difference approached statistical significance: higher rate of use of scheduled visits among the CP group in the 12 months after enrollment. No other group differences were present. About 40% of subjects used at least one visit for back pain after enrollment, and about 17% used some orthopaedic specialty care. (The HMO uses a "gatekeeper" approach to specialty care; orthopaedic care requires an initial referral from a primary care internist.)

Subjects' compliance with recommendations of the Back School was apparently not strongly affected by attendance. At 12 months after enrollment, 65% of the UC group reported that they had exercised for their backs more than "rarely" over the previous year, whereas among the LBS and CP attenders, respectively, 83% and 75% reported exercising more than rarely (chi square = 2.34; $df = 2$; $P = 0.31$). Attenders reported somewhat more frequently that they understood the causes of their back pain (67% of UC, 85% of LBS, and 80% of CP; chi square = 4.46; $df = 2$; $P = 0.11$).

Power Calculations

With essentially negative study findings, it becomes important to explore the probability of erroneously accepting the hypothesis of no treatment effect in this study. A conservative calculation of power is possible using the observed proportion of subjects with back pain at 12 months after enrollment in the UC group: 39%. Each treatment group contained about 66 subjects at the 12-month comparison. At a significance level of 0.05, using a one-tailed test, this study would have an 80% chance of detecting a halving of the proportion with pain (ie, to 20% of the group) and a 90% chance of detecting a reduction to 15%. Power is greater to detect differences through the analyses of covariance used repeatedly in this study.

DISCUSSION

This prospective, randomized trial failed to find an effect on pain or functional status among victims of LBP in an HMO using either a short, 4-hour psychoeducational group intervention or that intervention supplemented by an outreach program designed to encourage compliance with basic principles of self-management. Among patients with initial pain above the bottom tertile (ie, those with VAS scores of 2 or more) there was, if anything, a tendency for the two intervention groups to have less favorable pain status than a usual care control group at 12 months after intervention. Patients who received instruction did not achieve improvements in function measurable by the instruments used in this study.

Outreach after the initial intervention did appear to produce increased levels of utilization of scheduled health care visits; perhaps the outreach in this study made the HMO system look receptive and appetizing, leading to lower thresholds for use of care. Anecdotal reports from the LBS and CP group members who attended the Back Schools were extremely positive; subjects enjoyed the sessions, appreciated the communications in the CP package, and expressed very positive views about the instruction they received. In this study, however, the subjective sense of liking the interventions was not associated with measured improvements in pain or function.

These results are consistent with findings previously reported in randomized trials of Back Schools. Factory employees who received Back School instruction in a prospective trial by Bergqvist-Ullman and Larsson[3] did have shorter initial sick-leaves than controls, but that finding was not replicated in a controlled trial by Lindquist et al.[16] At least two controlled prospective studies have found no effect of Back School instruction on pain, function, or sick-leave at 1 year follow-up.[15,16] These disappointing results contrast dramatically with anecdotal patient testimony and reports from uncontrolled trials.[7,9,10,17]

In the current study, the Back School program, itself, was of

shorter duration than in most previously reported trials. At the low level of pain experienced by most of these HMO subjects, the motivation to attend multiple educational sessions produced extremely low attendance rates in the pilot phase. Thus, the Back school intervention tested here represents a compromise between theoretically ideal intensive instruction and the practical constraints of a real-world ambulatory health care setting.

From their own controlled trial and a review of the data, Lankhorst et al concluded that ". . . the Back School is of little value in the chronic phase of LBP and . . . is likely to give the greatest benefit in the early phase of ideopathic LBP."[15] The current study addresses just such an early phase of symptoms, and is nonetheless negative. The question then arises, is there any subgroup of LBP patients for whom Back School-type instruction is beneficial in terms of measurable outcome? If the answer is yes, it is probably so in a subgroup defined both on grounds of chronicity (early enough to be effective, but late enough to exclude those with a thoroughly benign natural course) and on grounds of functional impact (mild enough to benefit from exercise and ergonomics, but severe enough to be motivated to comply). We await such targeted intervention trials, with clear rules for patient selection.[4,21,28] One recent prospective controlled study of a three-session Back School has shown significant improvement among patients with chronic pain (mean duration, 7 years) on follow-up 16 weeks after instruction.[20]

As defined in this study, LBP appeared to have a more benign course than often reported in studies from consultative or tertiary settings. Although persistence of some pain was common, (present, for example, in half of all subjects at 18 months after enrollment) the level of severity for most subjects was low. At 18 months, SIP scores showed, on the average, virtually no functional impact from back pain, and only one subject in five reported any loss of work caused by back pain over a 2-week period at 18 months after initial enrollment. The benign average picture, however, obscures the important consequences of back pain for a small minority of our subjects. About 10% of subjects did report significant ongoing disability at the follow-up assessments. Special analyses of patterns of morbidity in this important subgroup are now underway.

Several of the assessment tools used in this study performed especially well for this ambulatory population, even using mailed administration. Response rates were high, and problems minimal, with the self-administered SIP, the VAS, clearly worded questions about disability from the Health Interview Survey, and the SCL-90. In each case, the instruments yielded scores with sufficient variation in the range of severity studies, and showed clinically sensible changes in functional status and pain over the follow-up period. The McGill Pain Inventory, conversely, was poorly understood by subjects in its mailed form, suffered from low completion rates, and seemed insensitive to pain in the range experienced by these study patients. Further studies of functional status will benefit from more extensive published reference values for the SIP and visual analogue formats. A shortened questionnaire using "back-related" items from the SIP recently had been tested successfully, and may offer a promising alternative to the full 136-item format.[25,26]

Overall, our results suggest that a short version of a Back School, with or without follow-up reinforcement contacts, is unlikely to affect the course of pain and disability for a relatively unselected group of victims of LBP in an ambulatory environment. Such programs may nonetheless be received warmly by those same victims, who not only enjoy the contact, but may even be led thereby to increase their utilization of ambulatory care over the subsequent year. Such "customer-oriented" health care programs may well yield dividends other than improvements in health status, but if a simple Back School program hopes to relieve pain and increase function, it will probably have to focus its efforts on a more highly selected subgroup of participants.

For the back pain sufferer, our message is basically an optimistic one. Over 90% of our relatively large outpatient sample improved with or without any special intervention. For these people, their back episode had minimal long-term sequelae and trivial functional impact. The natural history of back pain in the vast majority of our cases was quite benign and led to little long-term impairment. It is, however, the small population of victims, who are still suffering 6 to 18 months after an episode, toward whom we believe the most intensive research efforts now should be applied.

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