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Pitfalls of Patient Education: Limited Success of a Program for Back Pain in Primary Care

[Lumbar Spine]

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Outline

Graphics

Abstract^

Study Design: Low back pain patients seen in primary care were allocated randomly to one of two educational interventions or to usual care.

Objective: To evaluate educational interventions designed to improve the outcomes of primary care for low back pain.

Summary of Background Data: Patients with back pain are frequently dissatisfied with their medical care and identify lack of information as the most insufficient aspect.

Methods: In a large Health Maintenance Organization clinic, 293 subjects were allocated randomly to receive usual care, an educational booklet, or a 15-minute session with a clinic nurse, including the booklet and a follow-up telephone call. Outcome measures included satisfaction with care, perceived knowledge, participation in exercise, functional status, symptom relief, and health care use. Outcomes were assessed 1, 3, 7, and 52 weeks after the intervention.

Results: The nurse intervention resulted in higher patient satisfaction than usual care ($P < 0.001$) and higher perceived knowledge ($P < 0.001$). Self-reported exercise participation was also higher in the nurse intervention group after a 1-week follow-up period (97% *vs.* 65% in the other groups; $P < 0.0001$). There were no significant differences among the three groups in worry, symptoms, functional status, or health care use at any follow-up interval. Differences in self-reported exercise and perceived knowledge were no longer significant after 7 weeks.

Conclusions: These findings challenge the value of purely educational approaches in reducing functional impact or health care use related to back pain and also challenge the value of fitness exercise in the most acute phase of back pain.

Although back pain is one of the most common problems seen by primary care physicians,[21] satisfying and effective methods of dealing with these patients are elusive. Previous studies have found that musculoskeletal problems like back pain are among the problems most disliked by family physicians,[25,29] that many family physicians feel poorly prepared to manage back pain when they enter practice, and that family physicians do not feel that they have much to offer these patients.[6] Several studies have found low levels of patient satisfaction with primary care physicians' care for back pain,[7,11] especially compared with that provided by other health professionals, such as chiropractors,[7,24] nurses,[18] and physical therapists.[30]

One of the major deficiencies in primary care for low back pain has been the perceived inadequacy of information given to patients about their problem.[7,11] Providing patients with satisfying information is a particularly difficult challenge for back pain because accurate diagnosis is rarely possible and most common treatments are of uncertain value. The way in which information is presented, the amount and content may affect outcomes of care. For example, a randomized trial by a British general practitioner found that treating patients presenting with acute problems with a confident and positive approach as opposed to an uncertain one improved outcomes of care.[38]

These and other observations concerning the potential impact of the patient-provider relationship on outcomes of care [1,16,19,22] suggested that an intervention designed to boost physicians' back pain-related confidence, knowledge, and skills might improve their effectiveness with low back pain patients. A medical education intervention with this focus was developed and evaluated in a large family practice clinic.[8,9] Although the intervention succeeded in improving physicians' perceptions of their back pain-related comfort, knowledge, and confidence, it had no impact on patient satisfaction, symptoms, worry, function, or health care use.

The present study attempted to improve the effectiveness of primary care through educational interventions directed at the patient. Patient education is increasingly considered as a means of improving the quality and cost of care, but such efforts rarely have been evaluated rigorously in controlled trials. Previous educational efforts to improve outcomes of care for back pain in primary care patient populations have achieved mixed results. Berwick found that a 4-hour back class had no impact on patient symptoms or function and that it slightly increased health care use.[4] Roland found that an educational booklet on back pain emphasizing self-care increased patient knowledge and modestly decreased use during the subsequent year.[35] The present study evaluated the impact of a more proactive and patient-centered educational intervention for low back pain than had been tested previously in the primary care setting.

[black small square] Methods^

Study Site. The study was conducted between June 1992 and July 1993 at Group Health Cooperative

of Puget Sound, a staff model Health Maintenance Organization (HMO) serving more than 370,000 enrollees in western Washington state. All study patients were recruited in a suburban primary care clinic serving more than 35,000 enrollees and staffed by 23 family physicians, five physician assistants, and 19 registered nurses.

Study Design and Randomization Procedure. The present study compared three treatments for low back pain: usual care, usual care plus an educational booklet, and usual care plus an educational session with a registered nurse and the educational booklet. The initial plan was to randomize eligible patients to each of these groups. Experience from a pilot study indicated that some subjects assigned to usual care alone were very disappointed to not have received information they believed would have been useful.

Because of concerns that these feelings of disappointment could negatively affect outcomes, "preconsent" randomization was used. Before explaining the study to eligible patients, the research assistant would covertly use a list of random numbers to determine in which of two studies the patient would be invited to participate. One third of patients were invited to participate in a study of the outcomes of usual care for low back pain that did not involve any interventions (Figure 1). Patients agreeing to participate in this study represented the usual care control group. The remaining two thirds of patients were invited to participate in a study comparing two methods of providing back pain patients with information about their problem. Patients in the latter group who agreed to participate in the study were randomized to either the group receiving the nurse intervention or the group receiving the educational booklet. Although preconsent randomization is used infrequently and has raised concerns about deception, both institutional review boards with authority over the present study (Group Health Cooperative and the University of Washington) decided that concerns about possible deception were outweighed by the avoidance of substantial disappointment among subjects randomized to the usual care control group.

Figure 1. Randomization scheme and participation rates.

Patient Eligibility. Patients were initially eligible for the study if they were 20 to 69 years of age and were visiting the clinic for "back pain," "low back pain," "hip pain," or "sciatica." Final eligibility was determined by the treating physician or physician assistant who, at the end of the visit, either certified that the patient was eligible for the study or indicated one or more reasons for ineligibility. Reasons for exclusion were not: a low back problem (*e.g.*, thoracic, cervical, or shoulder pain), previous back surgery, systemic or visceral disease (*e.g.*, infection), known osteoporosis or corticosteroid therapy, pregnancy, cancer (other than skin), or unexplained weight loss, vertebral fracture or dislocation, progressive or severe neurologic signs, permanent disability or involvement in litigation, inability to speak English, and severe or disabling coexisting problems (including substance abuse).

Subject Recruitment. Patients determined to be eligible for the study were asked by the physician or

physician assistant if they would be interested in participating in a low back pain study. After covertly randomizing interested patients to either the “Outcomes” or to the “Educational Intervention” study, an assistant explained the appropriate study to the patient, obtained consent for interview and medical records review, and collected baseline data including back pain history, the nature and severity of their current back problem, and socio-demographic characteristics (Table 1). Subjects who agreed to participate in the study comparing two educational interventions were randomized to the booklet or the nurse.

Table 1. Baseline Characteristics of Study Subjects by Intervention Group

Educational Interventions. The primary goals of the educational interventions were to improve patients' understanding of their back problems and what they could do about them; to reduce unwarranted concern about serious outcomes; and to empower patients to take actions that could expedite a return to normal activities, reduce the risk of subsequent back problems, and minimize dependency on health care providers.

The two educational interventions were similar in content but different in method. The booklet, *Back in Action: A Guide to Understanding Your Low Back Pain and Learning What You Can Do About It*, was developed especially for the present study (copies available from authors). The booklet, based on current scientific knowledge, addressed back pain sufferers' concerns about the causes of their pain, their prognoses, the appropriate role of imaging studies and specialty referrals, and actions they could take to promote recovery and prevent recurrence. The booklet emphasized the value of returning to normal physical activities as quickly as possible and encouraged gradual increases in exercises such as walking, swimming, and riding a stationary bicycle. The booklet encouraged adoption of exercise goals and included a log for recording daily progress.

The other educational intervention was delivered by registered nurses practicing in the primary care clinic and included use of the booklet. Six female nurses with at least 20 years of clinical experience volunteered to participate in the study. These nurses received 9 hours of training on the management of low back pain including a 1-hour session on the management of back pain in primary care, 4 hours of relevant readings (including the booklet and references 7, 12, and 38), a 1-hour session on the rationale for the study, and a 1-hour session on elements of the intervention and the rationale for each. Lastly, after viewing a videotape of one of the authors performing the intervention, the nurses practiced it on each other until they could show they had mastered it.

The nurse intervention occurred immediately after the physician visit and was expected to last 20 minutes. The nurse first offered reassurance that although the pain may be great, the doctor had found no evidence of serious underlying disease. Next, the nurse answered the subjects' questions after asking the subject to review the booklet's table of contents to help identify areas of greatest concern. The nurse helped the subject set exercise goals (walking, swimming, or stationary bicycling) and

explained the importance of using the log included in the booklet to monitor progress. Finally, the nurse provided a “pep talk” emphasizing key points from the booklet, *i.e.*, if you hurt a little while exercising, it will not harm you but start gently, progress slowly, and be consistent; because each person is different, you must find what works best for you; and you are the most important person in achieving your own healing. One to 3 days later, the nurse telephoned the subject to answer questions, to reassure subjects they would get better with exercise and the passage of time, and to encourage subjects to begin or continue their exercise program.

Study Hypotheses. We hypothesized that subjects receiving the educational interventions would be more likely to: 1) understand the cause of their back problem and how to deal with it, 2) feel less worried about their back problem, 3) feel in control of their problem, 4) feel less bothered by their symptoms, and 5) be more satisfied with their care.

If the interventions changed subjects' perceptions, we further hypothesized that the interventions (compared with usual care) would lead to: 1) greater use of recommended exercise, 2) better physical and social function, 3) less disability, and 4) less use of health care services for back pain.

We also hypothesized that subjects randomized to the nurse education intervention would have more favorable outcomes than those randomized to the booklet alone, who in turn would have more favorable outcomes than those randomized to usual care. Finally, we hypothesized that any observed differences in perceptions or behaviors among the three groups would diminish with time, reflecting an extinguishing of the effects of the interventions and the natural history of back pain (which typically improves substantially within a few weeks, regardless of treatment received).[5,14,28,32,34]

Outcome Measures. The interventions were hypothesized to affect five specific dimensions of subjects' perceptions (*i.e.*, knowledge, worry, control, symptoms, evaluation of care) and four specific behavioral dimensions (exercise, function, disability, and health care use). A single primary measure of outcome was chosen for each of these dimensions, and secondary measures were included for several dimensions.

Perceived Knowledge. Subjects were asked how strongly they agreed (on a 5-point scale) with each of five statements concerning their perceived knowledge about various aspects of their back pain (*i.e.*, cause of pain, what to do to return to normal activities as quickly as possible, how to decrease future risk, what to do next time they have back pain, and specific activities or exercises that can help their back problem). Principal components analysis of baseline data using varimax rotation confirmed that these five items measured a single dimension (Cronbach's alpha = 0.83). A “Perceived Knowledge” scale was created by summing the scores of the five individual items and by transforming the resulting sum (ranging, 5-25) to a 0-100 scale, with 0 signifying least possible perceived knowledge and 100 signifying greatest possible perceived knowledge.

Worry. Subjects were asked to rate their “amount of worry or concern” about their back or leg pain during the past 24 hours on a 0-10 scale, with 0 signifying “no worry” and 10 signifying “extremely

worried."

Symptoms. The primary symptom measure evaluated the "bothersomeness" during the past 24 hours of low back pain, leg pain (sciatica), and lower extremity numbness or tingling. Subjects were asked to rate each symptom from 0 (not at all bothersome) to 10 (extremely bothersome). A single measure of symptom bothersomeness was created for each subject by selecting his or her score for the most bothersome symptom.

Control. Subjects indicated agreement (ranging from strongly agree [scored as 1] to strongly disagree [scored as 5]) with two statements assessing sense of control over their back problem. These statements were, "The next time I have back or leg pain, I will try to manage the problem myself without seeing a health care professional," and "I can control the extent to which my back or leg pain affects my life."

Evaluation of Care. Subjects were asked to rate seven aspects of the care they received for their back pain. Four aspects involved the information received, and the other three items pertained to provider concern, quality of treatment recommendations, and overall care received. Subjects rated each aspect from excellent (scored 5) to poor (scored 1). Principal components analysis confirmed that these seven items constituted a single scale (Cronbach's alpha = 0.89) with two subscales, "Information" and "General Care," which were highly correlated (r = 0.67). An overall score, "Evaluation of Care," and the two subscale scores were calculated by summing the scores for each item and transforming the result to a 0-100 scale (0 = worst and 100 = best). These satisfaction ratings were obtained only at baseline (for the index physician visit) and at a 1-week follow-up evaluation.

Exercise. The educational interventions encouraged subjects to quickly begin and gradually increase participation in regular aerobic exercise such as walking, swimming, or stationary cycling. At baseline, subjects were asked about aerobic exercise just before the onset of back pain, including days per week and duration of sessions. During follow-up interviews, subjects were asked the same questions but with reference to the previous week.

Function. A modified version of the Roland Disability Questionnaire [33] was used to assess physical and social function. This version excluded four items previously found to be minimally responsive to change and added three items from the Sickness Impact Profile [3] (from which the Roland items were drawn) found to be highly responsive. In addition, the new version clarified that the 23 yes-no questions pertained to back pain and leg pain (sciatica). This modification has been found to be reliable, valid, and responsive.[31]

Disability. The primary measure of disability was adapted from the National Health Interview Survey (NHIS).[2] Subjects were asked, "On how many days during the past (time interval) did back or leg pain (sciatica) cause you to cut down for more than half of the day on the things you usually do?" The 1-, 3-, and 7-week questionnaires queried about "cut days" during the time interval since the previous questionnaire. This permitted calculation of the proportion of subjects with any disability during the 7-

week period after the intervention and the mean number of limited activity days during that period. The 1-year interview asked about "disability days" during the previous 6 months.

Secondary measures of disability included two additional items from the NHIS and a question about workers' compensation. The NHIS items inquired about the number of days in bed for more than half the day ("bed days") and days lost from work or school for more than half the day ("work-loss days"). At 7-week and 1-year evaluations, subjects were asked if they were applying for or receiving any compensation for their back problem.

Health Care Use. During the 3-, 7-, and 52-week interviews, subjects were asked how many back pain-related visits they had made since the previous evaluation (or previous 6 months for the 1-year follow-up evaluation). Subjects were asked to report all such visits (including those to family physicians, specialists, physical therapists, chiropractors, and other providers) and hospitalizations.

Assessment of Outcomes. Short-term outcomes were assessed by telephone interviews 1, 3, and 7 weeks after the index visit. One-year outcomes were measured by mailed questionnaires. Subjects failing to return questionnaires within 2 weeks were interviewed by telephone. Interviews were blinded to study group assignment. Evaluations of the booklet or nurse interventions (part of the 1-week interview) came after all outcome questions had been asked.

Subjects' Evaluations of the Educational Interventions. During the 1-week interview, subjects indicating they had received the booklet were asked how much of it they had read and how useful they had found it. Subjects who said they spoke with the nurse were asked several questions about the helpfulness of the exercise program, the follow-up telephone call, and the session with the nurse overall.

Other Variables. Other baseline variables included socio-demographic characteristics, employment status, the SF-36 General Health Perceptions Scale,[40] six SCL-90 depression items,[10] smoking status, exercise history, and back pain history.

Analysis. The primary analyses tested whether outcomes were different in the nurse, booklet, and usual care groups. Chi-square tests were used for unadjusted comparisons of dichotomous baseline characteristics and outcome measures, whereas logistic regression was used to adjust for baseline differences. For continuous measures, analysis of variance was used for unadjusted comparisons, and analysis of covariance was used to control for baseline values. Change score analyses (not reported) were performed, yielding results similar to the analyses of covariance. The nonparametric Kruskal-Wallis test was used for unadjusted comparisons of continuous variables with non-normal distributions (such as provider visits and "disability days"). In all cases, the results of the Kruskal-Wallis test were consistent with those of the analyses of variance.

For all outcomes measures for which group differences were identified, analyses of covariance were performed using each specific sociodemographic variable as a main effect covariate. For the only

behavioral outcome significantly affected by the interventions (exercise), baseline perceptions measures (*e.g.*, perceived knowledge, worry, symptom bothersomeness) were also individually controlled for in the analysis of covariance. The conventional criterion for statistical significance, alpha < 0.05, was used.

For outcome variables with significant treatment effects, paired comparisons were performed to determine whether the two intervention groups differed from each other and whether either group differed from the usual care group. The Bonferroni procedure was used to adjust the criteria for statistical significance in these paired comparisons. In the few instances where items were missing in the calculated scales, we estimated scale scores when fewer than half the items were missing. This was done by imputing mean scores (for the available items) for the missing items.

[black small square] Results^

*Subject Recruitment^*

During the 13-month recruiting period, 852 patients aged 20-69 years visiting the clinic for low back pain were screened for eligibility. Fifty percent of these patients (422) were ineligible for the study because of major medical problems (12%), previous back surgery (6%), systemic or visceral disease (6%), physician considered patient inappropriate for unspecified reasons (6%), cancer or unexplained weight loss (3%), unavailable for follow-up interviews (2%), unable to speak or read English (2%), multiple reasons (7%), or other reasons (7%).

Thirty-nine (9%) of the remaining 430 eligible patients were excluded before the preconsent randomization phase because they were not interested in hearing about the study (Figure 1). One third (129) of the remaining 391 patients were “prerandomized” to the “Outcomes Study” (usual care), and the remaining two thirds (262) were prerandomized to the “Educational Interventions Study.” Seventy-six percent of patients agreed to participate in the Outcomes Study (98) and 77% (201) agreed to participate in the Interventions Study. Those randomized to the latter study were randomized to receive the nurse education (98) or booklet only (103).

Between one and three randomized subjects in each of the study treatment arms were excluded from follow-up evaluation (Figure 1) for the following reasons: subsequently identified benign spinal tumors (2), urinary tract infections (2), and manic-depressive illness (Figure 1). All but one of these were excluded within 1 week of randomization, leaving 294 subjects. Follow-up data were obtained from 276 subjects (94%) at the 1-week interview, 265 (90%) at 3-week evaluation, 266 at 7-week evaluation (90%), and 268 (91%) at 1-year evaluation. Follow-up data from at least one time point were obtained from 286 subjects (97%). Follow-up rates in the three intervention groups were similar ($P > 0.05$ by chi-square test) at all follow-up intervals.

*Baseline Characteristics of Study Population^*

Baseline characteristics of the 286 subjects for whom follow-up data were available are described in Table 1. Study subjects had a mean age of about 43 years and were almost equally divided between men

and women. Subjects were typically well educated, white, and married. A large majority of subjects had employment outside the home and claimed to like their work at least moderately. Few subjects considered their jobs to be very physically demanding, and only 6% were applying for or receiving compensation for their back pain.

Subjects averaged 78.5 points out of a possible 100 on the General Health Perceptions Scale of the SF-36 (Table 1), slightly higher than the norm for the noninstitutionalized US population.[27] Only 5% of subjects perceived their health as fair or poor. Subjects had scores similar to those of a representative sample of the GHC adult population on items concerning depressive symptoms.[39] Relatively few subjects were smokers, and more than two thirds reported regular aerobic exercise during the week before their current back pain.

About 25% of subjects were seeking care for back pain for the first time (Table 1), but 43% had histories exceeding 5 years. Most subjects entered the study at the first visit for their current episode of back pain, which had lasted less than 1 week in 59% of cases. Only 5% reported leg pain that was worse than back pain.

Baseline values for some of the outcome variables indicate a moderately high level of symptom bothersomeness, a moderate degree of worry, and, compared with other studies,[20,23] a relatively high degree of dysfunction according to the Roland Disability Questionnaire (Table 1). Only a minority of subjects claimed they would try to manage future episodes of low back pain without seeking professional help, although most believed they could control the extent to which their back problem affected their lives. Finally, on average, subjects felt moderately knowledgeable about their back problem and rated the care during their index visit just above the midpoint of a poor-to-excellent scale.

Randomization was successful in ensuring that the subjects randomized to each of the three treatment arms were similar in terms of almost all the baseline variables. This was confirmed for continuous variables by analysis of variance and the Kruskal-Wallis test. The only variables for which significant differences were observed were: visit was subject's first ever for low back pain, mean low back pain knowledge score, and the expectation that subject would try to manage next episode without professional help. Subsequent analyses were adjusted for these baseline differences.

Actual Content of the Nurse Education Intervention^

The nurses reported spending a mean of 17.0 minutes with each subject (range, 8-30 minutes). Seventy-three percent of subjects asked questions of the nurses, most commonly concerning self-care and other alternatives to medical care (41% of subjects with questions), exercise (27%), causes of back pain (16%), and physical therapy (15%). All but one subject agreed to begin an exercise program. Walking was the most popular choice of exercise (68%), followed by stationary bicycle (17%), swimming (8%), and combinations of these types of exercise (5%). Nurses successfully contacted 93% of subjects by telephone during the week after the index visit and spent a mean of about 6 minutes on the phone.

Patient Evaluations of Educational Interventions^

Table 2 summarizes patient evaluations of the educational interventions after 1 week. Responses were generally quite positive. Subjects in the nurse education group were much more likely to claim they had tried the exercises described in the booklet (74% *vs.* 45%; $P < 0.001$). More than two thirds of subjects found each component of the nurse intervention (booklet, discussion, and phone call) to be at least moderately helpful.

Table 2. Subjects' Evaluations of the Educational Interventions: 1 Week Follow-up Questionnaire

Patient Perceptions^

The educational interventions had a positive effect on two of the six measures of subjects' perceptions after 1 week (Table 3). After controlling for baseline differences, significant differences were noted among the three groups in subjects' perceived knowledge about their back problem. Pairwise comparisons revealed that the nurse and booklet groups had significantly higher levels of perceived knowledge than the usual care group but did not differ from each other. The nurse group had significantly higher levels of knowledge than the other groups 3 and 7 weeks after the intervention, but these differences were no longer significant after 1 year (Figure 2).

Table 3. Changes in Subjects' Perceptions, Exercise, and Function 1 Week After Intervention: Adjusted for Baseline Differences*

Figure 2. Perceived knowledge about back problem (adjusted for baseline).

After 1 week, patients in the nurse group rated the care for their current episode of back pain more highly than either the booklet or usual care groups, which did not differ from each other. Higher ratings of care in the nurse group were limited to the informational aspects of care. No differences were noted at any follow-up interval among the three groups in worry, bothersomeness of symptoms, or feeling able to control how pain affects life. After 1 week, subjects in the nurse group were more likely than those in the booklet group to indicate they would try to manage future back problems by themselves (Table 3), but this difference was not statistically significant and had disappeared after 3 weeks.

Impact of Interventions on Reported Exercise^

The nurse intervention had a substantial impact on the proportion of subjects reporting regular aerobic exercise (*e.g.*, walking, swimming, cycling, jogging, or active sports; Figure 3). In the week after the intervention, subjects in the booklet and usual care groups reported little change in exercise behavior, but the proportion of subjects reporting regular exercise in the nurse group jumped from 66% at baseline to 97%. The higher level of reported exercise in the nurse group persisted during the entire 1-year follow-up period but was no longer statistically significant 7 weeks after the intervention.

Figure 3. Percentage of subjects reporting regular aerobic exercise in prior week.

Among those reporting regular exercise during the first week after the intervention, subjects in the nurse group reported exercising the most days (mean = 5.2 days); those receiving usual care reported the fewest (3.6 days), and those receiving the booklet were in the middle (4.4 days; $P < 0.001$). However, reported minutes of exercise per day (for those reporting any exercise) was lowest in the nurse group (mean, 35 minutes) and highest in the usual care group (54 minutes; $P = 0.015$). Thus, subjects in the nurse group reported more days of exercise per week but fewer minutes of exercise per day. Nevertheless, among those reporting any exercise, the total amount of reported exercise during the week (*i.e.*, mean number of days × average minutes per day) was similar in the three treatment groups (183-193 minutes/week; $P = 0.70$).

Function and Disability^

The interventions had no effect on subjects' physical and social function (Roland score) 1 week after the intervention (Table 3) or at any other follow-up interval (data not presented). The proportion of subjects reporting any days of limited activity, bed rest, or work loss resulting from their back pain was similar in all groups (Table 4) at each follow-up interval. The mean number of disability days in each intervention group did not differ significantly. Too few subjects were receiving compensation (10 subjects at the 7-week follow-up evaluation and one after 1 year) to permit meaningful analyses.

Table 4. Disability Reported by Intervention Group, Time Period, and Disability Measure

Health Care Use^

The proportion of subjects making at least one visit for low back pain and the mean number of visits were similar for all groups at each follow-up interval (Table 5). Only one subject was hospitalized during the study period.

Table 5. Provider Visits for Low Back Pain by Intervention Group and Time Period

Effect of Controlling for Potential Confounders^

The significant intervention effects found in the present study (*i.e.*, greater perceived knowledge, higher ratings of information received, and increased likelihood of exercising) persisted after controlling for potential confounders.

[black small square] Discussion^

Our hypotheses were only partially confirmed. During the weeks immediately after the intervention, subjects receiving the educational interventions were more likely to perceive that they understood their back problem and were more likely to rate the information they received more highly. Although the nurse and the booklet interventions were superior to usual care alone, these differences were, with one exception, statistically significant only in the nurse group. The interventions had no effect on perceptions of symptoms, worry, or sense of control. Thus, the intervention appears to have succeeded in providing subjects with information that changed how they thought about their problem (*i.e.*, cognitive changes) but did not change how they felt about their problem (*i.e.*, affective changes).

The observed cognitive changes were associated with substantial changes in self-reported exercise activity. One week after the intervention, virtually all (97%) subjects in the nurse group reported they were exercising regularly, whereas the subjects in the other groups remained at preintervention levels (about 69%). Unfortunately, the reported increases in exercise were not associated with improvements in function or with decreases in disability or health care use. Possible explanations for this disappointing result include 1) subjects in the nurse group falsely reported they were exercising to appear compliant, 2) exercise benefited some subjects but harmed others, yielding no net effect, 3) the exercise was not of sufficient duration or intensity, or 4) the specific types of exercise used (*i.e.*, walking, swimming, and cycling) have no effect on the symptoms or function of persons with primarily acute back problems (87% had symptoms for less than 6 weeks). Benefits of exercise may be more apparent for patients whose pain persists beyond a few weeks (because the acute natural history is so favorable), and perhaps exercise is most beneficial when timed to begin after the most acute phase.

Improvements in perceived knowledge and reported exercise after the nurse intervention were greatest after 1 week but remained significant after 3 weeks. The intervention groups did not differ significantly on any outcome measure after 1 year. Thus, the present study provides no evidence that the nurse intervention has any lasting effects on how subjects perceive and respond to back pain.

Although it seems unlikely that a large fraction of subjects lied about their exercise to the blinded interviewer (who was not one of the nurses participating in the study), the extent of false reporting is unknown. Similarly, there is no way to determine whether compensating positive and negative effects of exercise canceled out each other. However, the possibility that exercise may not benefit patients with acute back pain is consistent with other studies. Two recent randomized studies have found no

benefit of one particular type of exercise-flexion.[15,17] Unfortunately, there have been few randomized trials of exercise for low back pain and none for aerobic exercise. There is little evidence favoring any particular exercise regimen, particularly for acute back pain.[13,26,36]

Unlike the only other randomized evaluation of a back pain booklet, which found a modest decrease in physician visits,[36] the booklet used in the present study had no effect on health care use. Both studies found significant increases in actual [36] or perceived (the present study) knowledge about back pain in the booklet group. Improved knowledge in the Roland study was still evident after 1 year, possibly because subjects referred to the booklet when responding to a mailed questionnaire.[36] In the present study, perceived knowledge was not significantly greater in either the nurse or booklet groups after 1 year.

The only other randomized trial that used purely educational interventions for back pain in primary care also failed to affect patient symptoms, function, or health care use.[4] Subjects whose back pain had persisted 2 weeks after a doctor visit were randomly allocated to usual care or a 4-hour “back school psychoeducational session” taught by an orthopedic nurse practitioner and a physical therapist. Patient knowledge, perceptions, exercise levels, or satisfaction with care were not measured. Unlike the Roland (1989) study, which found a decrease in health care use among subjects receiving an educational booklet, Berwick et al [4] found an increase in health care use. A randomized study of self-care brochures mailed to new enrollees in a HMO also suggested that patient education could increase use of health care for back pain.[37] The same study found increased health care use for sore throats and fever after enrollees were sent self-help brochures on these symptoms.

The nurse education intervention was designed to be practical for implementation in other settings if it was found effective. The time cost of training (about 9 hours of nurse's time plus 4-5 hours of time for the group training) was modest. Of greater consequence over the long run would be the time nurses spend with patients (about 30 minutes per patient including the follow-up phone call, costing about $15 in nurses salary and benefits) and the logistical problems of ensuring that nurses are able to meet with appropriate patients in a timely manner. The limited and short-term benefits of the intervention probably do not justify even these moderate costs. Although subjects had positive reactions to the booklet, this inexpensive (about $1.00) intervention alone had little measurable effect.

The present study has several notable strengths and limitations. The randomized design and relatively large sample size ensured that clinically important differences were identified and were the result of the interventions rather than baseline differences in the study groups. The high participation rate and broad inclusion criteria enhance the generalizability of the results to other similar settings. The high follow-up rates in all intervention groups make bias caused by dropouts unlikely. Finally, contamination of study groups was not a significant factor in the present study because the educational interventions were delivered immediately after randomization and were available only to the subjects assigned to receive them.

The main limitations of the present study were its restriction to one largely white and highly educated

HMO primary care practice, lack of validation of subjects' reports of exercise, and evaluation of only one particular educational approach. It is not clear how well these results would generalize to other settings, although it could be argued that this type of highly educated, active, and employed population would be the most likely to benefit from an educational intervention that encourages early activation. Alternatively, it could be argued that this population is so advantaged that it had little to gain from additional information. The substantial impact on reported exercise suggests that there was room for this patient population to “improve” in at least some respects.

In summary, the present study found that although back pain patients liked the educational interventions and may have benefitted from them in some ways, the interventions had no impact on symptoms, function, disability, or health care use. This was true despite increases in self-reported exercise. This adds to the growing evidence that some exercise regimens may not benefit patients with acute low back pain.

Because of the limited benefits, there is little justification for implementing this type of nurse education program in primary care. Although patients feel a need for more and better information about back problems, it is not clear how this can be accomplished cost-effectively. A previous effort to educate physicians to convey similar information to their back pain patients also had no impact on patient outcomes.9 Because back pain is typically a recurrent problem that improves with time regardless of treatment, effectively teaching patients to take more responsibility for their own care remains a high priority. Future efforts to promote self-care for back pain should first identify the underlying needs of persons with recurrent episodes of care and then develop intensive interventions that directly address these needs.

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