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Are Back Supports Plus Education More Effective Than Education Alone in Promoting Recovery From Low Back Pain?

Results From a Randomized Clinical Trial

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Study Design. Randomized clinical trial.

Objectives. To evaluate the effectiveness of a back support plus education *versus* education alone in promoting recovery from a work-related low back disorder (WR-LBD) while simultaneously considering personal, health, and occupational factors and the impact of occupational factors on recovery.

Summary of Background Data. No randomized studies of active industrial workers with low back disorders exist regarding the effectiveness of back supports plus education.

Methods. A total of 433 actively employed hourly union workers who had a recent diagnosis of a WR-LBD: 1) those who wore a specially designed back support plus received education on back health; and 2) those who received education on back health only. Demographic, health, medical, and occupational factors were obtained through interview or abstraction of computer files; individual ergonomic exposures were measured with a lumbar motion monitor. Outcomes evaluated over a 12-month period included: self-reported measures of back pain, back pain disability level, physical health, mental health, and administrative measures of recurrence, lost work time, and medical care utilization.

Results. There was no difference between the study groups with respect to mental or physical health, low back pain, back pain disability, neurogenic symptoms, lost work time, likelihood of recurrence of an episode of a back disorder, or other administrative measures of healthcare utilization or lost work time. However, significant decreases in low back pain, low back pain disability, neurogenic symptoms, and an increase in physical health were observed over the 12 months of observation in both study groups. The only occupational variable found to influence was plant group whereby service parts operations workers in the back support plus education group experienced a lower likelihood of WR-LBD recurrence.

Conclusion. Although there was no overall effect on self-reported recovery or administrative measures or lost work time between the study groups, a back support plus health education may have some value in preventing recurrent WR-LBD in industrial workers who work in psychosocial environments and perform manual material handling tasks similar to those found in parts distribution centers.

Key words: back pain, low back pain, randomized clinical trial, rehabilitation, back supports, education, occupational health, recurrent low back pain. **Spine 2007;32: 2050–2057**

Low back pain continues to be a widespread common problem often associated with major morbidity and disability. Low back pain is a major health problem in terms of its high prevalence, with 27.4% of U.S. general population of adults in 2003 experiencing for 1 day or more in the last 3 months.[1] Among employed persons, its prevalence can be notably higher reaching as high as 82% in nurses after only 5 years of employment in nursing.[2,3] The probability of cases recurring in 1 year may be as high as 44%.[4,5] In the United States, the most profound impact of low back pain emerges in the population of eligible age for employment where economic incentives (overtime) and disincentives (potential loss of job) are likely to compel only the most disabled into formal health care, leaving a high prevalence who continue working, negatively affecting productivity.[6,7]

There is a substantial literature examining various interventions for low back pain including medications, physical therapy, cognitive therapy, education, spinal manipulation, heat/cold therapy, exercise, back supports, and surgical interventions with none that show greater effectiveness than others.[8–10] Conflicting results have emerged for a variety of reasons including small samples, heterogeneity of the samples with respect to employed persons, lack of analysis of recurrence, and omission of important time varying covariates such as job exposures. Moreover, the focus of intervention trials on individuals from rehabilitation clinics or in-patient facilities may not produce results generalizable to employed persons where the problem of low back pain is

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widespread but characterized by a lower level of disability. Thus, in order to evaluate the effectiveness of population-based interventions for low back pain, the "treatment" must be low cost, easy to use, noninvasive, and with minimal side effects.

Back supports and education are 2 interventions that meet these criteria for population-based use. The literature on back supports provides little support for their use in field studies of primary prevention intervention.[11–17] and some support for its use in rehabilitation.[18] Laboratory studies have found that back supports increase intra-abdominal pressure,[19–21] increase muscular strength,[22] reduce biomechanical loading on trunk muscles during lifting and pulling tasks,[23–28] prolong the onset of fatigue,[29,30] reduce the spine motion during lifting,[27,31] and increase spine stability.[32,33] The use of back supports in clinical studies of individuals with low back pain has shown conflicting results in terms of trunk strength and endurance.[16,34,35] Relief of back pain by use of braces or corsets in small or nonrandomized clinical studies including samples of employed persons has been reported.[36–40] But the support for these findings has not been conclusive. The studies lending the most support toward lifting belt use have found small reductions in spinal compression, albeit with large individual differences including some individuals having increased spinal compression,[23] small changes in muscle recruitment in response to sudden loading,[25,26] the studies showing reductions in the spine kinematics during lifting,[27,31] and increased spinal stability with the back support use.[32] Even though a back support may not be effective as a primary prevention intervention, these studies suggest mechanisms by which a back support may serve as a secondary prevention intervention that could promote recovery and prevent back injury recurrence. These biomechanical findings could explain the Walsh and Schwartz[16] finding that a back support was beneficial in preventing back injury recurrence in grocery distribution center workers. These laboratory studies also are consistent with the limited evidence available through systematic reviews through 1999 conducted by van Tulder *et al*[18] in which no evidence was found regarding effectiveness of lumbar supports for secondary prevention, but some evidence that lumbar supports are more effective than no treatment. However, not identified through this review is whether back supports are more effective than other interventions for treatment of low back pain. Based on this, the authors conclude that high-quality randomized trials on the effectiveness of lumbar supports are warranted. Further, clinical research examining the role back supports can play in the treatment of low back pain is warranted because of the laboratory studies showing the potential for pain reduction with back support use through the mechanism of increased intra-abdominal pressure relieving spinal compression, reducing spinal impact from sudden loading during lifting, and increasing spine stability during trunk motions.

Education as an intervention for promoting back pain recovery has been evaluated in the form of a back school as well as printed materials and individualized instruction. Back schools focus on active participation in recovery and rely on physical conditioning and training. Evaluations of back schools for occupationally related back conditions have generally been favorable in terms of clinical outcomes but the quality of the studies are not high and this type of intervention requires significant involvement on the part of the patient and provider.[41–44] Education delivered through printed materials are designed to provide information and advice and, more recently, use a cognitive behavioral approach.[45] Booklets have been observed to be associated with less consultations for back pain,[46] but booklets whose content focused on general education or for self-care provided mixed evidence for pain reduction or disability and only marginal differences when compared with physical therapy or chiropractic.[47–50] Burton *et al* showed that an educational booklet aimed at changing beliefs and behavior can produced favorable clinically important changes for those with back pain although the employment status of the sample was not described.[45]

Although there have been 2 studies showing conflicting results for the use of back supports plus education in primary prevention,[15,16] no studies were identified that evaluated both interventions on recovery from low back pain.

One of the challenges in evaluating population-based intervention strategies is the variation in occupational exposures experienced by the sample. This study addresses the practical application of an unresolved question concerning recovery from low back pain where conflicting results, small samples heterogenous for employment, short-term follow-up, and deficient randomizations. Because of the large and geographically dispersed nature of the target patient population under study, it was imperative for population-based interventions to be used. The primary hypothesis tested was that there was no difference between the use of back supports plus education *versus* education alone on self-reported and administrative measures of recovery controlling for demographic, health, and occupational factors. The secondary hypothesis test was that occupational factors do not affect recovery.

■ Methods

Design. The study design was a randomized clinical trial stratified by plant to achieve balance in intervention group enrollment across 9 participating study plants in 3 states (Illinois, Michigan, and Ohio) from 3 automotive divisions (metal fabricating, truck assembly, and service parts operations [SPO]). The randomization and stratification scheme for the project were designed such that at all time intervals there was sample size balance in the study groups. The study investigators were blinded during the interim analyses of safety and efficacy of the study groups. The Institutional Review Boards of Rush University Medical Center and the Ohio State University approved the study protocol initially and the protocol continues to be monitored and reviewed annually.

Subjects. A total of 868 workers who were identified through a computerized corporate Health Information System (HIS) as having a nontraumatic work-related low back disorder (WR-LBD) without other work-related conditions were screened for the intervention study. The presence of a work-related low back disorder was determined by the plant's medical department. Eligibility for enrollment also required that the worker was within 8 weeks of the injury/illness date of diagnosis listed on HIS and had no concomitant work-related injury or illness at the time of the screening. Enrollment began October 16, 1998 first with hourly workers from the assembly center followed by those from the metal center, and then finally enrollment began on November 8, 2002 from the 7 SPO facilities. Follow-up of study participants concluded on November 5, 2004. The sample analyzed herein consisted of 433 hourly union workers who had at least 1 follow-up visit after the baseline visit.

Recruitment. Individuals identified through the HIS who met the screening eligibility criteria for diagnosis and time interval for diagnosis were sent a packet containing 2 letters: 1 jointly signed by the plant manager and local union shop chairman supporting participation in the study and the other from the principal investigator briefly describing the study. Workers then were contacted by telephone to confirm other eligibility criteria (*e.g.*, not pregnant, not postoperative, not retiring within 12 months, hourly employee) and to schedule a baseline visit. Of those screened, the refusal rate for participation was 15.7%. For individuals agreeing to participate, arrangements were made with the individual's supervisor to arrange coverage for the worker while participating in a study visit. Participants received their regular wages while engaged in study activities.

Randomization. Before randomization, all study participants signed informed consent and in addition, the sample in the SPO group signed HIPAA research forms. After the study subjects signed informed consent (and later HIPAA research consent), baseline measurements were obtained. After baseline measurements, participants were randomly assigned from a stack of randomization cards in opaque enveloped to 1 of 2 study groups, stratified by plant and by using our method of determining job risk of low back disorder in each of the categories of plants studied (assembly, metal center, and distribution centers).[51]

Intervention

Education. Participants in both study groups received a health education program delivered according to a script in the study office off the production floor by one of the trained staff under the supervision of a nurse. Health education was delivered by videos (each approximately 10 minutes in duration) and instruction based on brochures. The health education protocol was as follows: 1) baseline visit: a video on routine self-care activities during an acute episode of back pain and brochures on weight control, body fat, and physical activity; 2) 1-month follow-up visit: a video on good body mechanics and safe lifting practices at home and work and a booklet on blood pressure control; 3) 2-month follow-up visit: a video on avoiding risk factors for back problems and correct postures and a brochure on quitting smoking; 4) 6-month follow-up visit: a video focusing on exercises for back strength and flexibility and a brochure on stress management; and 5) 12-month follow-up visit: a brochure with pictures illustrating the back health techniques demonstrated in the videos viewed. Participants were given the brochures after each session. The content of the education during a particular study visit was based on epidemiologic data regarding the natural history of low back pain as well as knowledge of the factors known to affect recovery.[5] At the last study visit, a booklet was provided which summarized each of the individual back health topics covered.[52] The educational component of the study comprised on the average approximately 20 minutes or one half of the time during each study visit. For ethical reasons, it was determined that a group which was observed only could not be implemented within the context of this sample of actively employed hourly union workers.

Back Supports. The participants who were randomly assigned to receive a back support were fitted with a commercially produced back support (Ergodyne Proflex). The back support had a double layer construction comprised of an inner mesh layer with vertical plastic stiffeners sewn into the posterior mesh panel. The inner layer attached anteriorly with Velcro. The outer layer was composed of 2 offset elastic bands. The width of the elastic was 17 cm where the bands attached to the inner mesh center seam that would be positioned over the posterior midline and was 10 cm wide where the elastic on each side terminated at Velcro tab that attached to the front of the belt. The belt was tensioned by stretching the outer elastic. We had the manufacturer modify the belt in 2 ways. First, the belt was modified by sewing orange material over the tab on the elastic and by sewing an orange trim line on the belt itself so that it was easy to visually determine if the elastic was tensioned when a participant was wearing the belt. The orange trim line was intended to aid in the distant visual assessment of compliance with tightened the belt according to the protocol and serve as a reminder aid for the worker to tighten the belt into the position of the square trim line during work tasks as per protocol. The second modification to the belt was the removal of the shoulder straps from the belt so as to prevent the nonprotocol wearing of the device as a cloak rather than a belt.

Participants were measured during the baseline visit and fitted by a study staff member to ensure that the proper size was given. The participant then applied the back support under the supervision of the study staff member while receiving instructions on how to apply it. Participants were instructed to tighten the back support during job activities and to loosen it during breaks. They also received a booklet summarizing the instructions and care of the back support. Replacement back supports were available at no cost. At each study visit, questions were asked *via* structured interview regarding compliance with the use of the back support and any problems (*e.g.*, discomfort) associated with its use during work activities. Those in the back support group were reevaluated each visit regarding the fit, problems wearing the support (*e.g.*, discomfort, irritation, *etc.*), and the frequency of its use while at work. Compliance to the use of back supports was monitored by self-report with 78% using after 1-month and 51% using the back support as instructed at the 12-month study visit. No adverse effects associated with back supports were observed or reported by study participants. Direct observation of a worker's compliance with use of the back support while working was attempted during the monthly ascertainment of the location of the active cohort, but visualization of their use was not always feasible.

Measurement Protocol. Measured and self-reported information were collected during each study visit before the study intervention. The self-reported outcome measures were ascertained through a structured interview, which covered low back pain frequency and bothersomeness combined into a single score (range, 0 = no low back pain to 10 = low back pain extremely bothersome all the time), back pain disability (Oswestry Back Pain Disability Questionnaire, range, 0 = no back pain to 100 = completed bedridden from back pain),[53] physical health (Health Survey Short Form, SF-12, range, 13 to 69; higher values mean better physical health),[54] mental health (SF-12, range, 10 to 70; higher values mean better mental health),[54] neurogenic symptoms (American Academy of Orthopedic Surgeons, range, 0 to 100; higher values mean less neurogenic symptoms),[55] and other important covariates thought to influence the outcome variables. The categories of these covariates were: demographics, medical history, health habits, demographic, and occupational factors (related to job or plant) were also obtained from the baseline interview or from existing plant data files by a trained study staff. Psychological job strain was computed from a subset of items from the Job Content Questionnaire.[56] Height, weight, body fat percentage, waist, and hip circumference were obtained by direct measurement.

The administrative data outcomes evaluated in this study included: visits to the medical department for a low back problem, visits to a personal physician, recurrent low back pain episodes, OSHA restricted days, OSHA lost work days, and any injury or illness lost work days. These data are referred to as administrative because they pertained to the utilization of medical resources and were either directly abstracted either from a computerized health information system or a time and attendance personnel computerized databases or were obtained from a structured interview during each study visit. Only visits to medical departments for low back pain at the study plants were considered. Access to the HIS database allowed for continuous monitoring of medical visits, the purpose of the medical visits, and recurrent episodes of WR-LBD even though study participants may have missed a study visit and obviates the possibility of ascertainment bias from the additional study visit scheduled in the SPO sample. Our ascertainment of recurrent episodes is described in detail elsewhere.[4]

The quality of the summarized data and the study safety were monitored on a regular basis by the study clinical investigators who were blinded as to the study group.

Ergonomic exposure of the study participant's job was quantified using the Lumbar Motion Monitor (LMM) software and represented as a probability of a job as being high risk for low back disorders.[51] A total of 486 jobs were measured during the study. Workers who participated in the job assessments did not have a current WR-LBD, had experience with the job for at least 2 weeks, and signed informed consent for participation (and the SPO sample also signed HIPAA research consent). Jobs were ergonomically assessed at baseline, and each time the worker either changed jobs or the tasks associated with the current job were changed significantly. Job changes after baseline were monitored through the structured interview at each study visit, reports from supervisors, plant ergonomics teams, and monthly ascertainment of the active cohort. The plant ergonomics team, workers whose measurements were taken, and their supervisors received a copy of the ergonomic exposure report generated with each assessment.

Follow-up. After the baseline visit, follow-up visits for intervention study participants were 1, 2, 6, and 12 months later. A 9-month visit was added to the follow-up schedule for the SPO sample because of concerns about the possibility of attrition given small samples at each of the individual SPO facilities owing to the challenges of monitoring study participants give large distances among the facilities and within the plants themselves. After each study visit, the participant received a token of appreciation (*e.g.*, mug, tee shirt, *etc.*). There were a total of 1403 study visits after baseline.

Statistical Analyses. The statistical analyses followed the "intent-to-treat" principle.[57] Data summarization and bivariate analyses were performed using SPSS, version 11.0. Multivariate statistical analyses were performed using SAS statistical software (version 8 for personal computers). PROC MIXED for generalized estimating equations (Restricted Maximum Likelihood) estimation for estimating the variance/covariance matrix (Toeplitz covariance structure), PROC PHREG for Cox proportional hazards regression, and PROC LOGIST (for logistic regression) as appropriate to the model. Multivariate models of outcomes included age at enrollment into study and gender for conceptual reasons and exposure in terms of job risk for low back disorders because the original study hypothesis identified ergonomic exposure as an important covariate to consider in recovery from a work-related low back disorder. The LMM value closest to the outcome measure weighted for time was used in the sequence for computing the time varying exposure covariates.

Results

Characteristics of the Study Sample

There was no difference between the study groups with respect to demographic, health, or job characteristics. This was a predominantly white, middle-age male sample with a very high prevalence of cigarette smoking. The degrees of low back pain and back pain disability were at relatively low levels. A low level of physical health was noteworthy (Table 1).

Recovery Trends Based on Self-Reported Measures and Impact of Intervention

The self-reported outcome measures are displayed in Tables 2 to 6. Significant improvements in the study sample with respect to physical health and decreases in low back pain disability, low back pain, and neurogenic symptoms were observed over time (Tables 3–6). No change over time was noted for mental health (Table 2). There was no statistically significant effect of study group over time, that is, participants in 1 study group did not improve significantly more than the other group or no significant study group by time interactions for any of the self-reported measures.

Administrative Measures of Recovery and Impact of Intervention

There was no difference between the study groups with respect to number of visits to the medical department, visits to a personal physician, OSHA lost work days or restricted days, or lost work days due to any injury or illness.

The overall sample experienced a total of 117 recurrent episodes of a WR-LBD. The intervention group back support plus education was found to statistically

Table 1. Baseline Characteristics of the Study Subjects According to Intervention Group

Characteristic	Back Support Plus Education (N = 222)	Education Alone (N = 211)	All Subjects (N = 433)	*P*
Mean age (yr)	46.1 ± 8.0	46.1 ± 7.3	46.1 ± 7.6	0.958
Female	37 (16.7%)	50 (23.7%)	87 (20.1%)	0.068
Non-white	76 (34.2%)	79 (37.4%)	155 (35.8%)	0.487
Married	149 (67.1%)	140 (66.4%)	289 (66.7%)	0.866
High school education or higher	215 (96.8%)	205 (97.2%)	420 (97.0%)	0.850
Cigarette smoker	121 (54.5%)	117 (55.5%)	238 (55.0%)	0.843
Excellent/very good self-rated health	87 (39.2%)	101 (47.9%)	188 (43.4%)	0.069
Regular exercise outside work	135 (60.8%)	115 (54.5%)	250 (57.7%)	0.203
High stress	72 (32.4%)	56 (26.5%)	128 (29.6%)	0.179
Mean systolic blood pressure (mm Hg)	135.0 ± 15.2	133.1 ± 17.7	134.1 ± 16.5	0.226
Mean diastolic blood pressure (mm Hg)	85.7 ± 11.0	85.8 ± 11.2	85.7 ± 11.1	0.911
Mean body mass index (kg/m^2)	30.2 ± 4.8	29.6 ± 6.0	29.9 ± 5.4	0.204
Mean waist hip ratio	0.92 ± 0.08	0.92 ± 0.09	0.92 ± 0.09	0.253
Mean heart rate (beats/min)	75.0 ± 10.6	74.8 ± 10.2	74.9 ± 10.4	0.858
Mean percentage fat	21.9 ± 9.1	22.1 ± 10.1	22.0 ± 9.5	0.824
Mean mental health score	50.8 ± 10.1	50.0 ± 10.0	50.4 ± 10.0	0.465
Mean physical health score	40.6 ± 9.5	41.1 ± 9.6	40.8 ± 9.5	0.610
History of LBP	125 (56.3%)	129 (61.1%)	254 (58.7%)	0.418
>1 prior episode LBP	84 (37.8%)	91 (43.1%)	175 (40.4%)	0.330
Previous surgery for LBP	12 (5.4%)	8 (3.8%)	20 (4.6%)	0.334
Current episode of LBP				
LBP onset less than 2 wk ago	147 (67.4%)	145 (69.0%)	292 (68.2%)	0.720
Mean low back pain score	4.09 ± 2.69	4.18 ± 2.78	4.13 ± 2.73	0.733
Mean Oswestry score	24.4 ± 16.7	24.5 ± 15.9	24.5 ± 16.3	0.964
Mean neurogenic symptom score	78.9 ± 23.2	81.3 ± 19.7	80.1 ± 21.6	0.243
Any prescription medication for LBP	138 (62.2%)	142 (67.3%)	280 (64.7%)	0.264
Any narcotic or corticosteroid medication for LBP (%)	56 (25.2%)	68 (32.2%)	124 (28.6%)	0.107
Mean job risk of low back disorder (LMM)	38.5 ± 17.0	36.1 ± 16.0	37.3 ± 16.5	0.134
Very satisfied/satisfied with job	168 (75.7%)	166 (78.7%)	334 (77.1%)	0.510
Mean hours worked in past 7 days	48.4 ± 13.0	46.7 ± 14.4	47.6 ± 13.7	0.206
Mean psychological job strain scare	8.4 ± 3.9	8.0 ± 3.4	8.2 ± 3.7	0.182

Mental health scores range from 0 to 100 with higher scores indicating better mental health. Health scores range from 0 to 100, with higher scores indicating better physical health. Oswestry scores range from 0 to 100, with higher scores indicating higher back pain disability. Composite low back pain scores range from 0 to 10, with higher scores indicating extreme bothersomeness and high frequency. Neurogenic symptom scores range from 0 to 100, with higher scores indicating lower symptoms. Lumbar Motion Monitor values range from 0 to 100, with higher values denoting higher probability the job is high-risk for low back disorders. Psychologic job strain scores range from 3 to 12, with higher scores indicating higher strain.

reduce the rate of recurrent episodes of WR-LBD (23.1% *vs.* 31.1%, $P = 0.059$) (Table 7). However, when adjusted for age, gender, and exposure as measured by the LMM, the difference between the study groups was not significant (adjusted hazard ratio = 0.72; 95% confidence interval, 0.50, 1.04, $P = 0.085$) (Table 8). When considering occupational exposure by plant category, the total rate of recurrent events was 34.9% for the back support plus education group *versus* 63.1% in the education only group ($P = 0.016$) in the SPO plant grouping; in the manufacturing category, there was no difference between the study groups. This protective effect persisted after adjustment for individual level worker exposure as measured by the LMM (study group, with back support plus education as referent: odds ratio = 0.314; 95% confidence interval, 0.126, 0.783, $P = 0.011$; average moment LMM: odds ratio = 0.996; 95% confidence interval, 0.970, 1.026, $P = 0.784$).

Discussion

To the authors' knowledge, this is the first carefully designed randomized clinical trial conducted in an industrial setting of a tertiary intervention aimed at promoting recovery from a low back disorder. This study also simultaneously considered a panel of important risk and prognostic factors for this condition, including demo-

Table 2. Generalized Estimating Equations of Change in Mental Health* (SF-12) (n = 433)

Variable	Coefficient of Change (days)	*P*
Time	−0.00039	0.490
Age (yr)	−0.02894	0.535
Gender (male = 1)	2.45520	0.007
Exposure	−0.00895	0.551
Study group (back support = 1)	0.14117	0.863
Study group by time	+0.00128	0.669

*Higher values mean better mental health.

Table 3. Generalized Estimating Equations of Change in Physical Health* (SF-12) (n = 433)

Variable	Coefficient of Change (days)	*P*
Time	0.00614	<0.001
Age (yr)	−0.08588	0.065
Gender (male = 1)	2.61220	0.004
Exposure (LMM values)	0.02349	0.093
Study group (back support = 1)	−0.31727	0.698
Study group by time	0.00055	0.851

*Higher values mean better physical health.

Table 4. Generalized Estimating Equations of Change in Neurogenic Symptoms* (n = 433)

Variable	Coefficient of Change (days)	P
Time	0.0104	0.015
Age (yr)	−0.0579	0.567
Gender (male = 1)	4.6091	0.019
Exposure (LMM values)	0.0344	0.253
Study group (back support = 1)	−0.9871	0.576
Study group by time	−0.0033	0.587

*Higher values mean fewer neurogenic symptoms.

Table 6. Generalized Estimating Equations of Change in Low Back Pain Scores* (n = 433)

Variable	Coefficient of Change (days)	P
Time	−0.0036	<0.001
Age (yr)	−0.0219	0.111
Gender (male = 1)	−0.7514	0.005
Exposure (LMM values)	−0.0004	0.824
Study group (back support = 1)	−0.2479	0.306
Study group by time	+0.0015	0.091

*Lower values mean lower levels of low back pain.

graphic, health, medical, and occupational factors. This study did not find any overall differences between individuals in the back support plus education group and the group receiving only education regarding self-reported recovery measures of mental health, physical health, back pain, back pain disability, and symptoms, even when adjusting for age, gender, and job risk for low back disorder. There was no difference between the study groups with respect to OSHA lost days, OSHA restricted days, number of visits to the plant's medical department for WR-LBP, or total lost work days for any injury or illness. Despite lack of differences between the study groups, physical health improved, neurogenic symptoms, low back pain, and low back pain disability decreased over time on the average over the 12 months of observation among the study participants. Surprisingly, no change in mental health was noted possibly because of the overall high level of job satisfaction in this sample supporting the notion that the WR-LBD condition examined herein was truly related to physical occupational factors.

The study also investigated the impact of occupational factors on recovery from an episode of low back pain. No self-reported job factors were found to be statistically associated with recovery. Neither was the measured ergonomic job risk of low back disorder determined by the LMM found to impact any of the recovery measures.

It is possible that the improvement in physical health, the lessening of back pain symptoms, and reported decrease in back pain disability of the study participants were not due to the study intervention and merely a function of the duration with which they were observed. However, without information about the health status of a group of workers with low back injuries who did not receive an intervention, we cannot firmly draw this conclusion. While there is some evidence that supports the use of a back support,[22,25–27] those studies were typically conducted in well-controlled environments or a laboratory not in field settings.

When looking at the entire dataset, we found there was a trend for back supports plus education to reduce the likelihood of recurrent low back pain episodes. Further analysis revealed that this was due to a difference found in a subgroup of workers employed in the parts distribution operations. This finding is consistent with the study of Walsh and Schwartz[16] who also found that back supports had a benefit in preventing low back pain recurrence in a grocery warehouse operation, an operations similar to that found in SPOs. The reason for the effect in SPO workers could be due to the fact that these workers may have in the past experienced a higher cumulative past exposure than was measured for their current jobs. The difference may also be due to other unmeasured aspects of the study population not accounted for in this study, such as psychological factors. Recently, the possibility of lack of social support in the work environment has been put forth as a factor that could affect recovery.[58] Considering the aforementioned enormity of most SPOs and the relative isolation in which these workers function, it is plausible that there is some social interaction effect.[59] Jobs in the parts distribution centers were more autonomous, had less social interaction, and were much more self-paced relative to the production jobs in the line-driven manufacturing facilities, which are all psychosocial factors that have been linked to the etiology of low back pain.[5] It also could be that the nature of the lifting tasks in SPO facilities are more responsive to the therapeutic effect of a back support than in line-driven operation where job tasks are performed in stationary, fixed positions. Unbalanced lifting and mental

Table 5. Generalized Estimating Equations of Change in Oswestry Back Pain Disability Score* (n = 433)

Variable	Coefficient of Change (days)	P
Time	−0.01198	<0.001
Age (yr)	0.01520	0.843
Gender (male = 1)	−4.64997	0.002
Exposure (LMM values)	−0.02320	0.286
Study group (back support = 1)	−0.29833	0.825
Study group by time	0.00301	0.513

*Lower values mean lower back pain disability.

Table 7. Rate of Recurrent Episodes of Low Back Pain by Study Group

Recurrent Episode	Back Support + Education	Education Only	Total	P
No	170	146	316	
Yes	51 (23.1%)	66 (45.2%)	117	
Total	221	212	433	0.059

Table 8. Cox Multivariate Regression of Likelihood of Any Recurrent Episode of Low Back Pain (n = 433)

Variable	Hazard Ratio (95% CI)	*P*
Age (yr)	1.001 (0.98, 1.03)	0.911
Gender (1 = male)	0.563 (0.37, 0.86)	0.008
Exposure (LMM values)	0.998 (0.99, 1.01)	0.752
Study group (1 = back support)	0.721 (0.50, 1.04)	0.085

stress during lifting in laboratory settings have been found to result in large loads on the spine.[27,60] Given the above-referenced factors, the back support could have served more as a "reminder" effect in the SPO sample than in the line-driven samples.

Another possible mechanism for a protective psychologic effect of a back support could be on the perceived stress level. Stress can be physically manifest by ineffective energy mobilization, inefficient behavior, and overreactivity, which could have been mitigated with the application and use of the back support.[61] The overall prevalence of self-reported continuous or frequent stress was higher in SPO sample than in the manufacturing sample (34.9% v 29.6%), and our previous work identified stress to be a significant predictor of recurrence of work-related low back pain.[4] And stress may be manifest by higher levels of spinal load resulting from personality-job mismatch.[62] The literature is devoid of any other explanation or studies of the possible psychological effects specifically attributable to back support use in the work setting.

While we are not recommending back supports as a universal company-wide policy based on these findings, there may be a subgroup of injured automotive workers, namely, those in parts distribution centers, who could potentially benefit from their use. Aside from the effect of the intervention, this longitudinal clinical trial suggested that employed persons with a work-related low back problem could recover over a 12-month period. Thus, this randomized clinical trial also provides valuable insight into the natural history of low back pain. Our findings supports epidemiologic data that suggest that common symptoms associated with low back pain can resolved over time if not associated with sciatica or disability.[5] We used multiple measures of recovery outcomes recognizing the potential for the multidimensional nature of the origins and prognosis of low back pain. It was thus surprising not to see any improvement in mental health over time. This suggests that, in this industrial population, mental health is less likely to be a prognostic factor than physical health and thus interventions should be focused on the latter. The study results also provides new insight into the design of future randomized clinical trials of low back pain, namely, an important outcome to measure in any trial of recovery from low back pain should be its recurrence. That is, to break the cycle or chronicity of low back pain, interventions aimed at preventing recurrence and/or those who are at high risk of recurrence need to be devised. Or another way of saying this is that interventions for low back pain, acute or chronic forms, should not be judged regarding effectiveness until the follow-up period has been of sufficient to observe the impact on the recurrence rate. Lastly, although conducted in an industrial setting, this field randomized clinical trial with a sample of actively employed population in contrast to the majority studies of rehabilitation done in clinic populations provides some findings useful to managing this problem in many other sectors of employed persons.

■ Key Points

- Recovery from a work-related low back disorder can be observed by 12 months from diagnosis in terms of lower back pain, lower back pain disability, improved physical health, and less neurogenic symptoms.
- There is no impact of back supports plus health education on self-reported measures of recovery, lost work time, or medical care utilization.
- The use of a back support with health education may aid in reducing the likelihood of a recurrent work-related low back disorder in industrial workers in parts distribution centers.

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