SPINE Volume 28, Number 6, pp 533–541

Mini-Intervention for Subacute Low Back Pain

A Randomized Controlled Trial

Kaija Karjalainen, MD,* Antti Malmivaara, MD, PhD,* Timo Pohjolainen, MD, PhD,† Heikki Hurri, MD, PhD,‡ Pertti Mutanen, MSc,§ Pekka Rissanen, PhD,‖ Helena Pahkajärvi, RPT,* Heikki Levon, MD,* Hanna Karpoff, RN,* and Risto Roine, MD, PhD¶

Study Design. Randomized controlled trial.

Objectives. To investigate the effectiveness and costs of a mini-intervention, provided in addition to the usual care, and the incremental effect of a work site visit for patients with subacute disabling low back pain.

Summary of Background Data. There is lack of data on cost-effectiveness of brief interventions for patients with prolonged low back pain.

Methods. A total of 164 patients with subacute low back pain were randomized to a mini-intervention group (A), a work site visit group (B), or a usual care group (C). Groups A (n = 56) and B (n = 51) underwent one assessment by a physician plus a physiotherapist. Group B received a work site visit in addition. Group C served as controls (n = 57) and was treated in municipal primary health care. All patients received a leaflet on back pain. Pain, disability, specific and generic health-related quality of life, satisfaction with care, days on sick leave, and use and costs of health care consumption were measured at 3-, 6-, and 12-month follow-ups.

Results. During follow-up, fewer subjects had daily pain in Groups A and B than in Group C (Group A *vs.* Group C, $P = 0.002$; Group B *vs.* Group C, $P = 0.030$). In Group A, pain was less bothersome (Group A *vs.* Group C, $P = 0.032$) and interfered less with daily life (Group A *vs.* Group C, $P = 0.040$) than among controls. Average days on sick leave were 19 in Group A, 28 in Group B, and 41 in Group C (Group A *vs.* Group C, $P = 0.019$). Treatment satisfaction was better in the intervention groups than among the controls, and costs were lowest in the mini-intervention group.

Conclusions. Mini-intervention reduced daily back pain symptoms and sickness absence, improved adaptation to pain and patient satisfaction among patients with subacute low back pain, without increasing health care costs. A work site visit did not increase effectiveness. [Key words: subacute low back pain, randomized controlled trial, mini-intervention, work site visit, sick leave, costs, outcome] **Spine 2003;28:533–541**

Low back pain is considered a benign and self-limiting condition in most patients.[33] However, the high recurrence rate of pain episodes often causes long-term moderate pain and activity limitation,[10,37] leading to a chronic condition that burdens patients, employers, and health care and is associated with substantial economic losses.[11]

Returning to work and coping at the work site are often difficult for patients with prolonged low back pain.[22] Evidence suggests that multidisciplinary rehabilitation involving a work site visit helps patients with subacute low back pain return to work faster,[23,24,26] but the effectiveness of work site visits cannot be judged from existing scientific evidence. Although comprehensive lengthy multidisciplinary rehabilitation appears to be effective,[13–15,26] it may not be feasible for most patients. Indeed, simple interventions aimed at reducing patients' fears have been shown to reduce sick leave[12,21] among patients with subacute low back pain. However, in these studies, sick leave was the only outcome measure and clinical parameters were not reported.

The aim of the present study was to investigate the effectiveness and costs of a mini-intervention and the incremental effect of a work site visit for patients with disabling low back pain having lasted for 4–12 weeks, *i.e.*, subacute low back pain.

Materials

Patients were recruited from 36 primary health care centers in the Helsinki metropolitan area. A total of 350 general practitioners (GPs) were instructed to identify eligible patients. On finding a suitable and willing candidate, the GP informed the research nurse at the Finnish Institute of Occupational Health (FIOH), who telephoned the patient to ensure that the inclusion criteria of the study were fulfilled and arranged an appointment.

Inclusion criteria were as follows: 25–60-year-old employees with current daily low back pain (with or without sciatica), which had made working difficult for >4 weeks but <3 months (Table 1). Exclusion criteria were as follows: need for operative treatment, pregnancy, history of specific back disease (cancer, fracture, spondylarthritis, or infection), somatic or psychiatric disorder preventing rehabilitation, substance abuse, consulta-

From the *Department of Occupational Medicine, Finnish Institute of Occupational Health, †Social Insurance Institution, ‡ORTON Orthopedic Hospital, Invalid Foundation, the §Department of Epidemiology and Biostatistics, Finnish Institute of Occupational Health, and ¶Helsinki and Uusimaa Hospital Group, Helsinki, Finland, and the ‖University of Tampere, Tampere School of Public Health, Tampere, Finland.

Supported by the Social Insurance Institution of Finland.
Acknowledgment date: April 16, 2002. First revision date: August 6, 2002. Acceptance date: August 15, 2002.
The manuscript submitted does not contain information about medical device(s)/drug(s).
Other funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.
Address correspondence and reprint requests to Kaija Karjalainen, MD, Topeliuksenkatu 41 aA, FIN-00250, Helsinki, Finland; E-mail: kaija.karjalainen@occuphealth.fi

Table 1. Baseline Characteristics of the Subjects*

Characteristic	Mini-intervention Group (N = 56)	Work Site-Visit Group (N = 51)	Usual Care Group (N = 57)
Demographic features			
Age (yrs)	44 (25–60)	44 (25–60)	43 (25–59)
Females (%)	59	57	60
High school diploma (%)	41	28	33
Married (%)	43	49	42
Body mass index (kg/m^2)	27 (18–61)	27 (18–45)	25 (20–53)
Physical activity and general health			
Physical activity more than once a wk before back pain (%)	75	67	79
Self-rated health status for age very or quite good (%)	100	96	95
Pain and disability†			
Patients with sciatica (%)	69	69	68
Intensity of pain‡ (0–10)	6.2 (2–10)	5.4 (1–10)	5.7 (1–10)
Very or extremely bothersome pain during the past wk (%)	79	77	79
Pain has interfered quite a bit or extremely with work or daily life during past wk (%)	79	67	68
Functional status			
Days on sick leave in past 3 mos	15.8 (0–70)	14.7 (0–50)	15.0 (0–69)
Oswestry disability index§	36 (4–69)	33 (7–71)	34 (13–67)
Work-related features			
Blue-collar workers (%)	20	22	25
Satisfaction with own work (0–10)‖	7.5 (0–10)	7.1 (0–10)	7.1 (2–10)
Ability to work (0–10)¶	5.4 (0–10)	5.4 (0–10)	5.3 (0–9)
Working more than 1 hr daily in forward-bending position (%)	44	45	60
Work is slightly, very, or extremely burdensome physically (%)	55	71	72
Work is slightly, very, or extremely burdensome mentally (%)	79	78	75
Health-related quality of life			
15D#	0.85 (0.61–1.00)	0.86 (0.70–0.99)	0.86 (0.70–0.98)
Health care consumption during past 3 mos			
Visits to a physician	3.7 (0–20)	3.4 (0–12)	3.3 (0–18)
Visits to a physiotherapist	0.6 (0–8)	0.5 (0–6)	0.9 (0–12)
Satisfaction with overall medical care‖	4.5 (0–9)	4.2 (0–9)	4.1 (0–10)
Expectation of not recovering			
Subjective risk for not recovering (0–10)**	4.9 (0–10)	4.8 (0–10)	5.2 (0–10)

* Mean (range), unless otherwise stated. $P > 0.05$ on comparisons between the groups for each characteristic.
† Every patient had daily symptoms at baseline.
‡ Scored on an 11-point scale with 0 representing no pain at all and 10 unbearable pain.
§ Mean % of maximum score (45).
‖ Scored on an 11-point scale with 0 representing complete dissatisfaction and 10 complete satisfaction.
¶ Scored on an 11-point scale with 0 representing complete disability and 10 complete ability.
# Scale of 0.00–1.00, where 1.00 represents the best possible quality of life.
** Scored on an 11-point scale with 0 representing the lowest risk of not recovering and the 10 highest risk.

tion with a specialist in physical and rehabilitation medicine during the past year, inpatient rehabilitation for back pain during the last 3 years, 3 months of continuous sick leave resulting from back pain during the preceding year, and impossibility of a work site visit. Patients with prior back surgery were not excluded.

Randomization. Patients agreeing to participate were asked to complete baseline questionnaires at FIOH. The research nurse then randomized each patient into one of the three study groups; to ensure even distribution of patients regarding gender and age >45 and <45 years, four piles of sealed envelopes were used, and in each the randomization was done in blocks of 15. A biostatistician had prepared the order from a random number table. A secretary unconnected with the patients had numbered the envelopes sequentially to prevent their rearrangement. The research nurse and researchers were not aware of the block size and therefore could not predict the group assignments.

Interventions. All the patients visited FIOH once.

Mini-Intervention Group (A). The mini-intervention was based on current guidelines,[2,31,34,39] including features from a light mobilization program[20,21] and a graded activity program[24,25] reported earlier. Specific exercises recommended were based on studies on the function and well-being of the back.[1,17,18,27,35,36] A physician specializing in physiatry first interviewed and examined the patients in the mini-intervention group (n = 56) and encouraged them to ask anything unclear about their back pain. Working conditions were discussed and the results of the clinical examination explained to the patient and the radiograph findings and causes of pain clarified as far as possible.

The physician then introduced the patient, the main clinical findings, and the radiographs to a specialist in physiatry and a physiotherapist who confirmed the diagnosis and informed the patient of the good prognosis of the disorder and the importance of avoiding bed rest, remaining active, and exercising daily (*e.g.*, walking, bicycling, skiing). Sick leave was prescribed, if necessary. The patient, the physicians, and the physiotherapist mutually agreed about the essence of the rehabilitation.

The main aim of these consultations was to reduce the patients' concerns about their back pain by providing accurate information and to encourage physical activity. Typically, the first part lasted for 45 minutes and the latter part 15 minutes.

Table 2. Recommendations Given by the Back Specialist and Involvement of the Physiotherapist

	Mini-intervention Group (N = 56)	Work Site-Visit Group (N = 51)
Recommendation by the physician		
Sick leave (days) [mean (range)]	11 (0–26) SD (5.7)	12 (0–25) SD (8.1)
Advice to exercise	95	92
Exercising with weights	39	39
NSAIDs	34	31
Other analgesics	13	10
Other medicine	9	10
Back support	13	8
Group physiotherapy	20	20
Individual physiotherapy	18	14
Further examinations	16	18
Counseling or extra control visits	32	20
Modified work	11	12
Assessed and instructed by the physiotherapist		
Lifting	100	100
Sitting	100	100
Standing	100	100
Sitting down and standing up	100	100
Walking	88	88
Home exercises	88	92
Reaching out	57	57
Sleeping position	32	35
Weight exercise program	27	24
Housework and cleaning	25	24

Values are % unless otherwise indicated.
NSAIDs = nonsteroidal anti-inflammatory drugs.

The patient and the physiotherapist then appraised the patient's daily back-straining activities, such as lifting, sitting, standing, sitting down and standing up, walking, reaching out, sleeping position, and housework. Special movements required at the patient's work were trained if necessary. On the basis of individual need and motivation, the physiotherapist instructed the patient no more than five exercises for improving the function of deep abdominal muscles and establishing symmetric use of the back. Other daily exercises were planned feasible enough for the patient to commit to and execute them. The aim of this approximately 1.5-hour session was to increase body control and exercising in everyday life.

Feedback to the patient's GP included recommendations on further diagnostic tests, treatment, work, and sick leave. The GP at the patient's local health care center subsequently coordinated the recommended treatment in his/her usual manner at the health care center.

Work Site Visit Group (B). Intervention for the work site visit group (n = 51) by the physicians and the physiotherapist was identical to that in the mini-intervention group and performed without knowledge of final group assignment, which the research nurse confirmed just before the patient left FIOH (Table 2). The physiotherapist visited the patient's work site shortly after the FIOH appointment or his/her return to work. The patient's work supervisor and company nurse, physiotherapist, and physician were asked to join in the session. The aim of the visit, which lasted for approximately 75 minutes, was to ensure that the patient had adapted to the information and practical instructions of appropriate ways of using the back at work, to involve the supervisor and company health care professionals, and to encourage their cooperation. If needed, additional advice on back-friendly working techniques was given for the patient. Suggestions on purchase of specific equipment to the work site or the working environment were only given, if especially requested.

Feedback from the FIOH visit and a written report describing the substance and findings of the work site visit were sent to the patients' company physicians and to their GPs. The other participants of the work site visit were sent only a report on the work site visit. The patient was asked to give the report to his/her manager and encouraged to continue cooperation with the company health care. The company physician was advised to refer any patient who still had disabling low back pain or was on sick leave 3 months after randomization for inpatient rehabilitation.

Usual Care Group (C). Patients in the usual care group (n = 57) were not examined at FIOH but did receive a leaflet on back pain[28] (as did all other study patients). They were treated by their GPs in primary health care in the usual manner, including specialist consultations and physiotherapy, when necessary. They were not restricted from seeking specialist treatment privately, *i.e.*, at their own expense if they so wished.

Follow-up. All patients in each study group (except for one in the usual care group, who, without explanation, decided to withdraw from the study at the 3-month follow-up) were followed up by questionnaires 3, 6, and 12 months after randomization.

Outcomes. The main outcomes were sick leave resulting from back pain, intensity of pain (rated 0–10) back-specific disability (Oswestry),[8,9] generic health-related quality of life (15D),[32] frequency and bothersomeness of pain, interference of pain with daily life,[7] health care consumption resulting from back pain, and patient satisfaction with overall medical care (rated 0–10). The patients also answered questions about their work, exercising, health care consumption, and back pain-related expenses.

Economic Analysis. For the economic analysis, the type and amount of drugs prescribed were estimated from the questionnaires and valued at current market prices. Use and costs of health care services were recorded from the patients' reports. Unit costs of health care services were derived from market prices where possible or from health services producers (Table 3). The total costs were analyzed using the human capital method[19] with the Kruskal-Wallis nonparametric test.

Table 3. Prices Used in Economic Analysis

	Dollar Amount*
Mini-intervention	181
Mini-intervention plus work site-visit	250
Direct health care costs	
Visit to general practitioner or occupational physician	72
Visit to specialist physician	117
Visit to physiotherapist	31
Visit to nurse	30
Hospitalization (per day)	323
Rehabilitation (per day)	179
Indirect costs	
Absenteeism from work (per day)	152

* Official average exchange rate in 1999: USD 1.00 = FIM 5.5787.

Table 4. Results on 3-, 6-, and 12-Month Follow-ups* [mini-intervention group (A), work site-visit group (B), and usual care group (C)]

Variable	FU	(A)	(B)	(C)	A *vs.* C†	B *vs.* C†
Intensity of pain†‡§	3 mos	4.1 (0–9)	3.5 (0–10)	4.1 (0–9)	−0.1 (−0.9–0.7)	−0.2 (−1.0–0.6)
	6 mos	3.7 (0–8)	3.6 (0–8)	3.7 (0–10)	$P = 0.783$	$P = 0.687$
	12 mos	3.8 (0–8)	3.2 (0–9)	3.7 (0–10)		
Daily symptoms‖	3 mos	18%	19%	38%	0.3 (0.1–0.7)	0.4 (0.2–0.9)
	6 mos	13%	18%	25%	$P = 0.002$	$P = 0.030$
	12 mos	4%	8%	13%		
Very or extremely bothersome pain during the past week‖	3 mos	29%	35%	48%	0.5 (0.3–0.9)	0.7 (0.4–1.4)
	6 mos	20%	26%	34%	$P = 0.032$	$P = 0.315$
	12 mos	20%	27%	29%		
Pain has interfered quite a bit or extremely with work or daily life during past week‖	3 mos	25%	25%	35%	0.5 (0.2–1.0)	0.5 (0.3–1.1)
	6 mos	16%	22%	34%	$P = 0.039$	$P = 0.088$
	12 mos	14%	10%	23%		
Oswestry disability index‡¶	3 mos	20 (0–44)	22 (0–78)	25 (0–76)	−2.5 (−7.2–2.1)	−0.9 (−5.7–3.9)
	6 mos	19 (0–56)	19 (0–53)	21 (0–51)	$P = 0.289$	$P = 0.718$
	12 mos	19 (0–62)	18 (0–62)	19 (0–51)		
15D‡#	3 mos	0.889 (0.7–1.0)	0.888 (0.6–1.0)	0.870 (0.6–1.0)	0.01 (−0.01–0.03)	0.00 (−0.02–0.02)
	6 mos	0.900 (0.6–1.0)	0.891 (0.6–1.0)	0.888 (0.7–1.0)	$P = 0.295$	$P = 0.834$
	12 mos	0.881 (0.6–1.0)	0.888 (0.6–1.0)	0.892 (0.7–1.0)		
Satisfaction with medical care (0–10)‡**	3 mos	6.2 (1–10)	6.1 (0–10)	4.1 (0–10)	1.5 (0.7–2.4)	2.0 (1.08–2.9)
	6 mos	5.9 (0–10)	6.4 (0–10)	4.3 (0–10)	$P = 0.001$	$P < 0.001$
	12 mos	5.9 (0–10)	6.7 (0–10)	4.1 (0–10)		
Days on sick leave††	12 mos	19 (0–250)	28 (0–279)	41 (0–270)	$P = 0.019$	$P = 0.071$

* At 3 months: A (n = 56), B (n = 48), and C (n = 56), at 6 months: A (n = 56), B (n = 50), and C (n = 54), at 12 months: A (n = 56), B (n = 49), and C (n = 56), if not otherwise stated.
† The between group significance, odds ratio (95% confidence interval) and *P* value, has been calculated for the entire follow-up period using the repeated measures analysis with a baseline and time factor, except in the case of sick leave.
‡ Mean (range).
§ Scored on an 11-point scale with 0 representing no pain at all and 10 unbearable pain.
‖ Dichotomous outcome. Percentages in each group.
¶ Mean % of maximum score (45).
# Scale of 0.00–1.00. 1.00 represents the best possible quality of life.
** Scored on an 11-point scale with 0 representing complete dissatisfaction and 10 complete satisfaction.
†† Statistical significance (*P* value) of cumulative days on sick leave after randomization was calculated only for patients who returned all follow-up questionnaires. Sick leave was not controlled for with the baseline findings. Significance between the groups analyzed with Kruskal-Wallis nonparametric test. A (n = 55), B (n = 46), and C (n = 51).
FU = follow-up.

The costs of all ambulatory health care visits (to physicians, physiotherapists, nurses), days of inpatient hospital care, rehabilitation, medication, diagnostic tests, and radiologic examinations were all included in direct health care costs. Data on sick leave, health care consumption, and costs were used for the cumulative analysis only from patients who returned all follow-up questionnaires (Tables 4 and 5).

Statistics. Power calculations were carried out before the study to attain a power at least equal to 0.80 at the 0.05 significance level. A clinically significant difference between the groups in the primary outcome, pain intensity (on a scale of 0–10), was considered to be 1.5 (standard deviation 2.5). Accordingly, 45 patients per group and a total of 135 subjects were needed.

Table 5. Health Care Consumption and Costs During 1-Year Follow-up* (intervention included) [Mini-intervention group (A), worksite-visit group (B) and usual care group (C)]

Variable	(A)	(B)	(C)	A vs. C	B vs. C
	N = 56	N = 47	N = 54		
Visits to physicians	7 (1–42)	6 (1–25)	6 (0–49)	$P = 0.745$	$P = 0.449$
Visits to physiotherapists	5 (1–71)	6 (2–34)	6 (0–42)	$P = 0.290$	$P = 0.025$
Health care costs†‡	1024 (181–6303)	1024 (250–7714)	1351 (0–7485)	$P = 0.562$	$P = 0.714$
Costs of diagnostic tests and radiological examinations†	47 (0–466)	41 (0–414)	119 (0–1563)	$P = 0.077$	$P = 0.038$
Days as hospital inpatient	0.1 (0–4)	0.4 (0–6)	0.3 (0–7)	$P = 0.374$	$P = 0.596$
Days in inpatient rehabilitation	0.3 (0–14)	1.4 (0–21)	1.6 (0–24)	$P = 0.026$	$P = 0.525$
Health care and sick leave costs†§	4208 (181–41226)	4833 (250–43739)	7760 (0–45408)	$P = 0.075$	$P = 0.098$

* Mean (range). Significance between the groups analyzed with Kruskal-Wallis non-parametric test.
† USD. Official average exchange rate in 1999 USD 1.00 = FIM 5.5787
‡ Costs of: visits to physicians, physiotherapists and nurses, days at inpatient care in hospital, rehabilitation, diagnostic tests, x-rays and medication.
§ Cost of a day on sick leave: 152 USD.

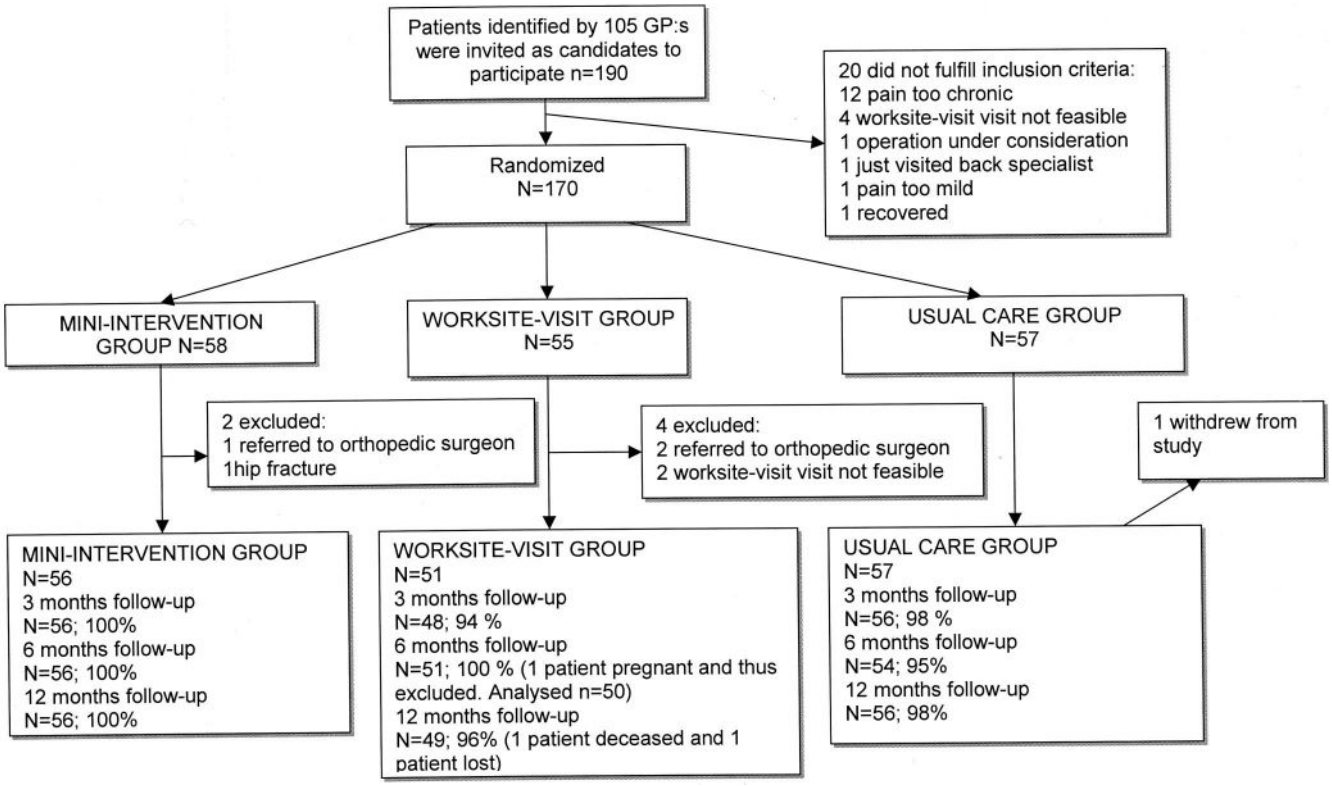

Figure 1. Patient flow during the study.

Patients were included in the analysis on the basis of their intervention group allocation. Missing questionnaires or values in questionnaires were not substituted for, except in the series of questions on quality of life (15D), in which a missing value was estimated from the other answers using regression analysis.

Because of skewed distribution of the data, the Kruskal-Wallis nonparametric test was used to analyze means and medians of continuous outcomes. Percentages for dichotomized outcomes were calculated using cross tabulation. Computations were performed using SPSS 10.0 for Windows software.

Statistical Methods for the Repeated-Measures Analysis. A structured analysis method for repeated measures was used to analyze the continuous response data (*i.e.*, repeated observations at follow-up times of 3, 6, and 12 months). Unstructured correlation for the repeated measures was used in all analyses. Group–variable interactions with the time factor were first tested (and were in all cases nonsignificant). The group comparisons were analyzed with the model, including the time factor and baseline information, using the mixed procedure of the SAS system.[30] We used the restricted estimation method for maximum likelihood and "satterth" specified as the method for computing the denominator degrees of freedom for the tests of fixed effects.

For binary responses we used the Generalized Estimating Equations method to analyze our repeated-measures data. This method enabled us to include the correlation structure of the repeated measures in the analysis. In the Generalized Estimating Equations method, the mean response is modeled as a logistic regression model, implying the odds ratio as the effect measure. The unstructured correlation structure was also used in this analysis. We used the SAS/STAT program[30] to analyze the continuous and binary response variables.

Ethical Considerations. The ethical committees of FIOH and the participating Helsinki metropolitan cities (Helsinki, Espoo, and Vantaa) approved the study. Patients were provided detailed written and oral information about the study and the interventions according to the Declaration of Helsinki[38] before being asked to sign an informed consent.

■ Results

Study Population

Between August 1998 and May 2000, 164 patients were enrolled in the trial: 96 women (58%) and 68 men (42%). Figure 1 shows the patient flow and reasons for exclusion. In total, 98% of the included patients provided follow-up information useful in the effectiveness analysis at each follow-up. At baseline, patients were comparable in each treatment arm (Table 1).

Interventions and Cointerventions

The physiotherapist visited the work site of 49 of 51 patients in the work site visit group; two patients needed to change their jobs because of back pain, and in these cases visits were not carried out. In 86% of the cases the patient's work supervisor and in 82% at least one person from the occupational health care (nurse, physiotherapist, or physician) attended the work site visit. At three work site visits, there was no participation from the employer or occupational health care side. Work site visits

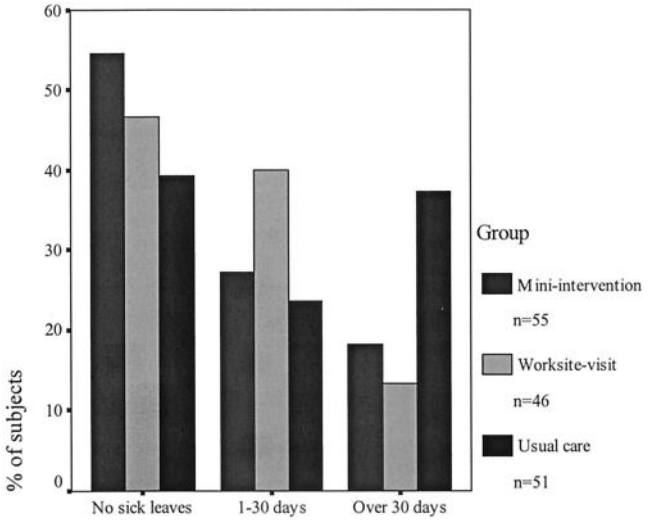

Figure 2. Cumulative days on sick leave during the 12-month follow-up.

incorporated the following: ergonomic lifting (in 65% of visits), sitting (67%), reaching out (61%), standing (47%), sitting down and standing up (31%), and walking (8%). In addition, based on work site assessment, minor adjustments were made in 51% of the visits.

Two patients in each study group had spine surgery during the 12-month follow-up. Cointerventions, such as visits including the use of alternative medicine services, were equally distributed among the three groups.

Outcomes

At all three follow-ups, the numbers with daily pain were smaller in both intervention groups than in the usual care group (A *vs.* C, $P = 0.002$; B *vs.* C, $P = 0.030$) (Table 4). Furthermore, when comparing the mini-intervention group with the usual care group, pain was less bothersome (A *vs.* C, $P = 0.032$; B *vs.* C, $P = 0.315$) and interfered less with daily activities (A *vs.* C, $P = 0.039$; B *vs.* C, $P = 0.088$) in the mini-intervention group. However, there were no clinically or statistically significant differences between the three treatment arms regarding intensity of pain, Oswestry disability index, or generic health-related quality of life (Table 4).

During the 12 months of follow-up, patients in the intervention groups had spent fewer days on sick leave (average in the mini-intervention group 19 days; work site visit group 28 days) than the controls (41 days) (A *vs.* C, $P = 0.019$; B *vs.* C, $P = 0.128$) (Table 4; Figure 2). The median for sick leave was 0 days for the mini-intervention group, 1 day for the work site visit group, and 7 days for the usual care group (A *vs.* C, $P = 0.043$; B *vs.* C, $P = 0.189$).

The intervention group patients were more satisfied with overall medical care than the controls during the entire 12-month follow-up (A *vs.* C, $P = 0.001$; B *vs.* C, $P < 0.001$) (Table 4).

Health Care Consumption and Costs

In the mini-intervention group only one patient had been in inpatient rehabilitation compared with seven patients in the control group and four in the work site visit group. The costs of diagnostic tests and radiologic examinations were significantly smaller in the work site visit group than in the usual care group. The direct health care costs were $359 (U.S.) less in the mini-intervention group and $163 (U.S.) less in the work site visit group compared with controls, but these differences were not statistically significant. When adding costs of the sick leave into the direct health care costs, total costs were $3552 (U.S.) less in the mini-intervention group and $2927 (U.S.) less in the work site visit group compared with the usual care group (Table 5).

There were no statistically or clinically significant differences between the mini-intervention and the work site visit groups with respect to clinical or economic outcomes.

■ Discussion

Our results show that a mini-intervention by a physiatrist and physiotherapist in the subacute phase of low back pain has a positive impact on patients' symptoms, satisfaction with medical care, and sick leave (Figure 2), whereas an additional work site visit does not improve clinical outcome. Because the mini-intervention and the work site visit were the only additions to usual care in the intervention groups of our study, we can confidently say that simple early specialist consultation with recommendations of further care has a positive impact on the recovery of patients with subacute low back pain. The results of the intervention might have been even more impressive had the patients in each treatment arm not received an information booklet on the treatment of back pain.[16] It must be admitted, though, that previous data on the effectiveness of using an information booklet as treatment for low back pain are conflicting.[3–5,16,29]

Two strengths of our study are the simple design of the trial and the high follow-up percentages (94–100%) in each group. Blinding of patients and therapists is challenging in these types of trials[38] and are often deemed impossible. We were able to blind the patient and therapist with respect to group assignment until the end of the consultation at FIOH, enhancing the credibility of the results. The facts that the two interventions were compared with usual care, *i.e.*, the conventional way of treating low back pain in the public health care system of Finland, and that the patients were recruited from the standard patient material of the Helsinki Metropolitan area GPs, make the results, in our opinion, generalizable also to patients with back pain from other countries.

Although back pain is one of the most common health problems, we had problems with recruiting patients from busy GPs. Only 105 of the 350 informed GPs were able to provide patients to the study (typically, one or two patients each). Our decision to inform a large pool of GPs of the study thus turned out to be correct and en-

sured successful recruitment of patients. Patients came from an equal mix of the 36 participating health care centers (considering the size of the centers) and, to our understanding, represent a typical sample of Finnish patients with subacute back pain. Although it is possible that the GPs might have referred to the study more often patients who they thought would benefit from the intervention, the study population represents, to our understanding, fairly well the average case mix of primary care patients, at least those to whom it is pertinent to send for specialist care.

For practical reasons the physician intervention was performed by two physicians (one specializing in physiatry and one board-certified specialist). We are confident, however, that the results would have been the same had only one certified specialist been involved in the intervention, as it was essential that physicians and physiotherapists truly interested in the patient's concerns performed the intervention at FIOH. Previous studies have shown that pain-related fear may be more disabling than pain itself,[6] and the reassuring and fear-reducing effects of being taken seriously by interested professionals may consequently be one explanation for the high patient satisfaction with treatment observed in our study (Table 4).

Patients in the work site visit group were the most satisfied with the treatment, presumably because of the additional attention they received. Because the outcomes for the mini-intervention group were more favorable than those for the work site visit group, this high patient satisfaction was not directly reflected in clinical outcomes. Patients seemed to have learned how to cope with their back pain at the time of their visit to FIOH. It may be that the patients in the work site visit group may have taken less responsibility for their own well-being, knowing the involvement of the company health care and the possibility for inpatient rehabilitation. Such an attitude may be counterproductive for recovery. Another possible explanation for the discrepancy is the fact that the work site visit concentrating on just one worker's job and well-being may have created an unpleasant and envious atmosphere at the patient's work site and interfered with his/her personal relationships with coworkers. Nevertheless, more research on effectiveness of different types of work site interventions is needed.

In accordance with previous studies,[12,20,21,24,26] the positive results in our study emerged in terms of fewer days on sick leave. In the two most similar trials to ours,[12,20,21] sick leave was the only outcome. Admittedly, sick leave is perhaps the most important outcome of back pain studies because of its enormous economic burden on society. The main aim of our mini-intervention was to encourage patients to carry on with their normal life and work as normally as possible despite the pain. This approach worked, as patients in the intervention groups (A and B) spent much less time on sick leave than the controls. The fact that the mini-intervention with a fairly small biomedical component reduced also the self-reported occurrence of daily pain and made symptoms less irritating without lessening the intensity of the pain indicates that prolonged low back pain with long-term time loss might be considered more a psychosocial problem with a medical aspect rather than a medical problem with psychosocial aspect.

New treatments are these days required to be cost-effective before being adopted into routine use. To allow for the estimation of costs, visits to health care, medication used, laboratory and radiologic examinations, and possible use of alternative medicines were all recorded in a similar manner in the three groups of the study. Even considering only direct health care costs, the mini-intervention turned out to be cost saving compared with conventional treatment. The cost-saving potential of the mini-intervention was even enhanced when the costs of sick leave were also taken into account. Based on these results, it seems that by investing a little to the early efficient intervention of subacute low back pain, considerable long-term savings can be expected.

■ Conclusion

In conclusion, mini-intervention by a physician specialized in back pain and a physiotherapist involving clinical examination, information, support and simple advice, reduced daily symptoms, and sickness absenteeism led to better treatment satisfaction and adaptation to pain compared with the usual care for patients with subacute low back pain. This was achieved by adding mini-intervention to long-term usual care, and it did not lead to any extra health care costs. The accompanying work site visit did not improve the clinical effect.

■ Key Points

- A mini-intervention by a physiatrist and a physiotherapist involving clinical examination, information, support and simple advice, reduces daily symptoms and sickness absenteeism as well as increases treatment satisfaction and adaptation to pain for patients with subacute low back pain.
- A work site visit appears not to add clinical effectiveness to the mini-intervention.
- Mini-intervention as a part of regular treatment of subacute low back pain reduces costs.

Acknowledgments

The authors thank Marja-Leena Sankari, Guy Ahonen, Kaj Husman, Risto Ihalainen, Aulikki Pitkänen, Monika Fredriksson, Ulla Kilpeläinen, Taina Murros, Irma Gerstenmaier, Saija Pohjolainen, Petri Karjalainen, Jaro Karppinen, Inga-Lill Lindström, Alf Nachemsson, Seppo Sarna, Simo Taimela, and Eira Viikari-Juntura, Gothenburg's Rygghälsan, the heads of health care centers in the Helsinki metropolitan area who had a great impact to trial implementation on the study and this article, and Richard Burton for language editing of the manuscript.

References

1. Adams MA, Hutton WC. The effect of posture on the role of the apophysial joints in resisting intervertebral compressive forces. J Bone Joint Surg Br 1980;62:358–62.
2. Bigos S, Bowyer O, Braen G, et al. Acute low back problems in adults (clinical practice guideline no. 14). Agency for Health Care Policy and Research, Public Health Services, U.S. Department of Health and Human Services, December 1994.
3. Burton AK, Waddell G, Tillotson KM, et al. Information and advice to patients with back pain can have a positive effect: a randomized controlled trial of a novel educational booklet in primary care. Spine 1999;24:2484–91.
4. Cherkin DC, Deyo RA, Battie M, et al. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. N Engl J Med 1998;339:1021–9.
5. Cherkin DC, Deyo RA, Street JH, et al. Pitfalls of patient education: limited success of a program for back pain in primary care. Spine 1996;21:345–55.
6. Crombez G, Vlaeyen JW, Heuts PH, et al. Pain-related fear is more disabling than pain itself: evidence on the role of pain-related fear in chronic back pain disability. Pain 1999;80:329–39.
7. Deyo RA, Battie M, Beurskens AJ, et al. Outcome measures for low back pain research: a proposal for standardized use. Spine 1998;23:2003–13.
8. Fairbank J. Use of Oswestry Disability Index (ODI). Spine 1995;20:1535–7.
9. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000;25: 2940–53.
10. Ferguson SA, Marras WS, Gupta P. Longitudinal quantitative measures of the natural course of low back pain recovery. Spine 2000;25:1950–6.
11. Frymoyer JW, Cats-Baril WL. An overview of the incidences and costs of low back pain. Orthop Clin North Am 1991;22:263–71.
12. Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? Spine 2000;25:1973–6.
13. Haldorsen EM, Indahl A, Ursin H. Patients with low back pain not returning to work: a 12-month follow-up study. Spine 1998;23:1202–8.
14. Haldorsen EM, Kronholm K, Skouen JS, et al. Multimodal cognitive behavioral treatment of patients sicklisted for musculoskeletal pain: a randomized controlled study. Scand J Rheumatol 1998;27:16–25.
15. Haldorsen EM, Kronholm K, Skouen JS, et al. Predictors for outcome of a multi-modal cognitive behavioural treatment program for low back pain patients: a 12-month follow-up study. Eur J Pain 1998;2:293–307.
16. Hazard RG, Reid S, Haugh LD, et al. A controlled trial of an educational pamphlet to prevent disability after occupational low back injury. Spine 2000;25:1419–23.
17. Hides JA, Stokes MJ, Saide M, et al. Evidence of lumbar multifidus muscle wasting ipsilateral to symptoms in patients with acute/subacute low back pain. Spine 1994;19:165–72.
18. Hodges PW, Richardson CA. Delayed postural contraction of transversus abdominis in low back pain associated with movement of the lower limb. J Spinal Disord 1998;11:46–56.
19. Hutubessy RC, van Tulder MW, Vondeling H, et al. Indirect costs of back pain in the Netherlands: a comparison of the human capital method with the friction cost method. Pain 1999;80:201–7.
20. Indahl A, Haldorsen EH, Holm S, et al. Five-year follow-up study of a controlled clinical trial using light mobilization and an informative approach to low back pain. Spine 1998;23:2625–30.
21. Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered: a randomized clinical trial. Spine 1995;20:473–7.
22. Jensen RC. Epidemiology of work-related back pain: a summary of job factors. Top Acute Care Trauma Rehabil 1988:1–15.
23. Karjalainen K, Malmivaara A, van Tulder M, et al. Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults (Cochrane review). Cochrane Database Syst Rev, 2000;3.
24. Lindström I, Öhlund C, Eek C, et al. The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioral approach. Phys Ther 1992;72:279–93.
25. Lindström I, Öhlund C, Eek C, et al. Mobility, strength, and fitness after a graded activity program for patients with subacute low back pain: a randomized prospective clinical study with a behavioral therapy approach. Spine 1992;17:641–52.
26. Loisel P, Abenhaim L, Durand P, et al. A population-based, randomized clinical trial on back pain management. Spine 1997;22:2911–8.
27. Malmivaara A, Hakkinen U, Aro T, et al. The treatment of acute low back pain: bed rest, exercises, or ordinary activity? N Engl J Med 1995;332: 351–5.
28. Malmivaara A, Pohjolainen T. Selkäkipuisen Käsikirja [in Finnish]. Suomen Selkäliitto 1996:18.
29. Roland M, Dixon M. Randomized controlled trial of an educational booklet for patients presenting with back pain in general practice. J R Coll Gen Pract 1989;39:244–6.
30. SAS Institute Inc., SAS/STAT. Users' Guide, version 8. Cary, NC: SAS Institute Inc., 1999.
31. SBU report on back pain. Stockholm: Swedish Council on Technology Assessment in Health Care, 1998.
32. Sintonen H. The 15D-measure of health-related quality of life. I. Reliability, validity and sensitivity of its health state descriptive system. In: National Centre for Health Program Evaluation (Working Paper 41). Melbourne 1994 (can be downloaded from www.chpe.buseco.monash.edu.au)
33. Waddell G. Volvo award in clinical sciences: a new clinical model for the treatment of low-back pain. Spine 1987:12:632–44.
34. Waddell G, Feder G, McIntosh A, et al. Low Back Pain Evidence Review. London: Royal College of General Practitioners, 1996.
35. Wilke HJ, Wolf S, Claes LE, et al. Stability increase of the lumbar spine with different muscle groups: a biomechanical in vitro study. Spine 1995;20: 192–8.
36. Vleeming A, Mooney V, Dorman T, et al. Movement, Stability, Low Back Pain: The Essential Role of the Pelvis. London: Churchill Livingstone, 1997.
37. Von Korff M, Saunders K. The course of back pain in primary care. Spine 1996;21:2833–9.
38. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. JAMA 2000;284:3043–5.
39. New Zealand Acute Low Back Pain Guide. Wellington, New Zealand: Accident Rehabilitation and Compensation Insurance Corporation (ACC) and the National Health Committee, 1997.

Point of View

Glenn Pransky, MD, MoccH

Low back pain (LBP) is a common, usually self-limiting, and medically benign condition.[2,3] However, restrictions in physical activity from this condition are often associated with disability and work loss, especially in industrialized countries; in the United States alone, LBP disability accounts for more than $55 billion in costs.[1] In

From the Center for Disability Research, Liberty Mutual Research Center for Safety & Health, Hopkinton, Massachusetts.
The manuscript submitted does not contain information about medical device(s)/drug(s).
No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Address correspondence and reprint requests to Glenn Pransky, MD, MoccH, Liberty Mutual Research Center for Safety & Health, 71 Frankland Road, Hopkinton, MA 01748, USA; E-mail: glenn.pransky@libertymutual.com

patients with chronic LBP, intensive multidisciplinary biopsychosocial interventions are effective in reducing disability;[4] more recently, these approaches have been applied to patients earlier in the disablement process. The mini-intervention reported by Karjalainen *et al*[9] focused on resolving patient concerns and encouraging activity, extending the findings of Indahl *et al*.[8] Although pain levels were similar across all groups, the intervention resulted in sustained decreases in concerns about pain and less LBP interference with activity.

The mini-intervention also addressed several workplace issues that have been linked to prolonged disability,[5,19] with approaches that have been effective in other studies.[12,13,20] Each patient had a discussion about work limitations, avoidance of sick leave, how to handle physically challenging work activities, with feedback to the general practitioner, and receipt of a booklet about living with LBP and avoiding disability. The study demonstrates that medical providers can facilitate return to work, in a sample of patients representative of common medical practice.

The failure of the work site visit component to provide additional reduction in pain or disability is not surprising. At least 25% of study participants had no significant work limitations as a result of their LBP, and many had not lost time from work. The low prevalence of recommendations for modified work reported here might be an indicator of how few patients actually would have benefited from workplace intervention. Other workplace intervention trials have been restricted to patients whose LBP directly interfered with work, as evidenced by being on disability.[2,7,8,10,13,18] Furthermore, the workplace visit effect may have been overshadowed by other work-related components of both intervention arms. Whether a subset of patients benefited from the work site intervention would be difficult to discern without large patient samples or more precise work outcome measures.[11,15,17,22]

More importantly, it is possible that the work site intervention was too brief or failed to include the elements of success that have been suggested by prior studies. Whereas some conclude that work site interventions do not improve return to work in subacute LBP,[7,22] others disagree.[3,10,23] Several studies suggest that collaborative problem-solving, ergonomic job modification, alternative duty job availability, improved physician–employer communication, and ongoing support lead to earlier return to work in subacute LBP.[3,10,14,16,25] Multicomponent interventions that combine a supportive employer response and continual contact with the injured worker appear to be most effective.[2,12,24] The approach used here, with instruction on "back-friendly working techniques" and how to lift, sit, and stand, was ineffective in other studies.[23] Purely medical approaches, such as improving adherence to established guidelines for care, or medical case management without linkage to the workplace, also have little, if any, positive effect.[6,21]

More research is certainly needed, not necessarily to develop new paradigms for disability reduction but to extend current knowledge about disability prevention to a greater number of patients.[5] In this context, the study by Karjalainen *et al*[9] represents an important contribution to our knowledge about effective approaches to restoring normal function in all aspects of the lives of our patients with LBP.

References

1. Andersson GB. Epidemiology of low back pain. Acta Orthop Scand Suppl 1998;281:28–31.
2. Bernacki EJ, Guidera JA, Schaefer JA, et al. A facilitated early return to work program at a large urban medical center. J Occup Environ Med 2000;42: 1172–7.
3. Buckle P, Stubbs D. The contribution of ergonomics to the rehabilitation of back pain patients. J Soc Occup Med 1989;39:56–60.
4. Cutler RB, Fishbain DA, Rosomoff HL, et al. Does nonsurgical pain center treatment of chronic pain return patients to work? A review and meta-analysis of the literature. Spine 1994;19:643–52.
5. Frank JW, Brooker AS, DeMaio SE, et al. Disability resulting from occupational low back pain: II. What do we know about secondary prevention? A review of the scientific evidence on prevention after disability begins. Spine 1996;21:2918–29.
6. Greenwood JG, Wolf HJ, Pearson RJ, et al. Early intervention in low back disability among coal miners in West Virginia: negative findings. J Occup Med 1990;32:1047–52.
7. Guzman J, Esmail R, Karjalainen K, et al. Multidisciplinary rehabilitation for chronic low back pain: systematic review. Br Med J 2001;322:1511–6.
8. Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered: a randomized clinical trial. Spine 1995;20:473–7.
9. Karjalainen K, Malmivaara A, Pohjolainen T, et al. Mini-intervention for subacute low back pain: a randomized controlled trial. Spine 2003;28:000–000.
10. Krause N, Dasinger LK, Neuhauser F. Modified work and return to work: a review of the literature. J Occup Rehabil 1998;8:113–39.
11. Lindstrom I, Ohlund C, Eek C, et al. The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioral approach. Phys Ther 1992;72:279–90.
12. Linz DH, Ford LF, Nightingale MJ, et al. Care management of work injuries: results of a 1-year pilot outcome assurance program. J Occup Environ Med 2001;43:959–68.
13. Loisel P, Abenhaim L, Durand P, et al. A population-based, randomized clinical trial on back pain management. Spine 1997;22:2911–8.
14. Loisel P, Gosselin L, Durand P, et al. Implementation of a participatory ergonomics program in the rehabilitation of workers suffering from subacute back pain. Appl Ergon 2001;32:53–60.
15. Malmivaara A, Hakkinen U, Aro T, et al. The treatment of acute low back pain: bed rest, exercises, or ordinary activity? N Engl J Med 1995;332: 351–5.
16. McLellan RK, Pransky G, Shaw WS. Disability management training for supervisors: a pilot intervention program. J Occup Rehabil 2001;11:33–41.
17. Pransky G, Benjamin K, Hill-Fotouhi C, et al. Work-related outcomes in occupational low back pain: a multidimensional analysis. Spine 2002;27: 864–70.
18. Schmidt SH, Oort-Marburger D, Meijman TF. Employment after rehabilitation for musculoskeletal impairments: the impact of vocational rehabilitation and working on a trial basis. Arch Phys Med Rehabil 1995;76:950–4.
19. Shaw WS, Pransky GS, Early prognosis for low back disability: intervention strategies for health care providers. Disabil Rehabil 2001;23:815–28.
20. Symonds TL, Burton AK, Tillotson KM, et al. Absence resulting from low back trouble can be reduced by psychosocial intervention at the work place. Spine 1995;20:2738–45.
21. Verbeek JH, Van Der Weide WE, Van Dijk FJ. Early occupational health management of patients with back pain: a randomized controlled trial. Spine 2002;27:1844–51.
22. Verbeek JH. Vocational rehabilitation of workers with back pain. Scand J Work Environ Health 2001;27:346–52.
23. Waddell G. Volvo award in clinical sciences: a new clinical model for the treatment of low-back pain. Spine 1987:12:632–44.
24. Wood DJ. Design and evaluation of a back injury prevention program within a geriatric hospital. Spine 1987;12:77–82.
25. Yassi A, Tate R, Cooper JE, et al. Early intervention for back-injured nurses at a large Canadian tertiary care hospital: an evaluation of the effectiveness and cost benefits of a two-year pilot project. Occup Med (Oxf) 1995;45: 209–14.