The Effect of Graded Activity on Patients with Subacute Low Back Pain: A Randomized Prospective Clinical Study with an Operant-Conditioning Behavioral Approach

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Research Report

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The aim of this study was to determine whether graded activity restored occupational function in industrial blue-collar workers who were sick-listed for 8 weeks because of subacute, nonspecific, mechanical low back pain (LBP). Patients with LBP, who had been examined by an orthopedic surgeon and a social worker, were randomly assigned to either an activity group (n=51) or a control group (n=52). Patients with defined orthopedic, medical, or psychiatric diagnoses were excluded before randomization. The graded activity program consisted of four parts: (1) measurements of functional capacity; (2) a work-place visit; (3) back school education; and (4) an individual, submaximal, gradually increased exercise program, with an operant-conditioning behavioral approach, based on the results of the tests and the demands of the patient's work. Records of the amount of sick leave taken over a 3-year period (ie, the 1-year periods before, during, and after intervention) were obtained from each patient's Social Insurance Office. The patients in the activity group returned to work significantly earlier than did the patients in the control group. The median number of physical therapist appointments before return to work was 5, and the average number of appointments was 10.7 (SD=12.3). The average duration of sick leave attributable to LBP during the second follow-up year was 12.1 weeks (SD=18.4) in the activity group and 19.6 weeks (SD=20.7) in the control group. Four patients in the control group and 1 patient in the activity group received permanent disability pensions. The graded activity program made the patients occupationally functional again, as measured by return to work and significantly reduced long-term sick leave. [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;72:279–293.]

Key Words: *Backache; Conditioning, operant; Exercise; Industry.*

Low back pain (LBP) usually has a benign course.[1–3] Eighty percent of patients with acute LBP will recover within 6 weeks.[4] Despite this, the socioeconomic impact is still considerable and increasing.[1,5] Few randomized prospective studies have been performed to show the effectiveness of any treatment methods used for patients with LBP of more than 8 weeks' duration, a fact also emphasized in the report of the Quebec Task Force on Spinal Disorders.[6] These patients are at considerable risk of developing chronic LBP.[4,6]

Comprehensive programs for patients with LBP have been reported to restore function.[4,7–14] Mayer et al[7] described an inpatient 3-week program with a multidisciplinary intervention.[7] Hazard et al[8] have repeated the program of Mayer et al. Cairns and Pasino[9] reported on an inpatient study that compared verbal reinforcement and feedback in the operant treatment of disability. Sirkoski[10] reported on an outpatient clinical model with an algorithm showing the suggested sequence of physical therapy. Catchlove

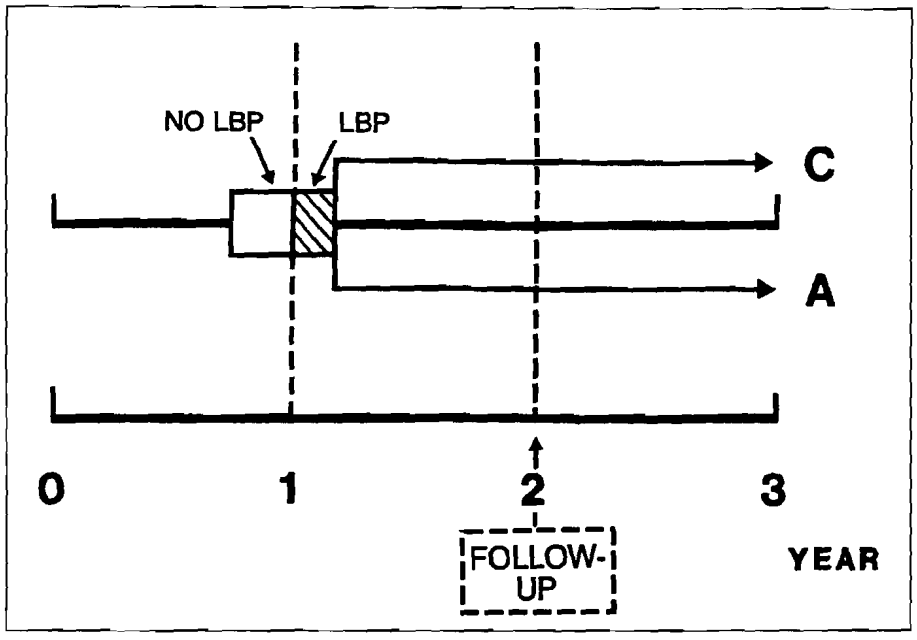

Figure 1. *Design of the study. Sick-leave records for all patients with low back pain (LBP) in both activity (A) and control (C) groups were obtained from the Social Insurance Offices for a 3-year period: 1 year before intervention (0–1), the intervention year (1–2), and 1 year after intervention (2–3). One year after intervention, a follow-up examination was performed.*

and Cohen[11] reported the effects of a directive return-to-work approach in a retrospective study of outpatient care and a number of treatment modalities, including directed return to work. Mellin et al[12] reported on a 3-week program of inpatient and outpatient treatment with a 2-week program of additional treatment. Mitchell and Carmen[13] reported on a multicenter study of 12 clinics with a treatment program including pain relief, mobilization, increased movements, muscle strengthening, further strengthening, and work conditioning. Meade et al[14] compared chiropractic and hospital outpatient treatments. The reported comprehensive programs are of different kinds, however, and have been directed at patients with different durations of LBP. The studies cited also used different outcome variables, such as pain, activity, return to work, functional capacity, physical capacity, straight leg raising, lumbar mobility, compensation costs, and different inclusion criteria for patients.

This article describes a graded activity program for patients with subacute LBP evaluated in a randomized prospective clinical study with 2 years' follow-up. The study compared traditional medical care (A Nachemson, C Bengtsson; personal communication) (control group) and traditional medical care combined a graded activity program (activity group). The aim of this study was to determine whether graded activity restored occupational function and facilitated return to work in a sample population of industrial blue-collar workers who were sick-listed for 8 weeks because of subacute, nonspecific, mechanical LBP. Although this research was part of a study with a broader purpose, the sole focus of this article is on graded activity with an operant-conditioning behavioral approach. The primary outcome measures were the rate of return to work and the amount of sick leave during the second follow-up year.

Method

Patients

One hundred three patients with subacute LBP (35% immigrants from Finland, 40% immigrants from other countries) were randomly assigned to either an activity group (39 men, 12 women) or a control group (32 men, 20 women). The blue-collar worker population (N=10,000) of the Volvo Company of Göteborg, Sweden, was 77% male and 23% female and included 16% immigrants from Finland and 16% immigrants from other countries. The patients in this study represented 13 different countries. The immigrant patients were not

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This study was approved by the ethical committee of the Medical Faculty of the University of Göteborg.

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Table 1. *Results of Prerandomization Tests Performed by Patients (N=103) During Evaluation by the Orthopedic Surgeon*

	Activity Group (n=51)		Control Group (n=52)		
	$\bar{X}$	SD	$\bar{X}$	SD	P[a]
Age (y)	39.4	10.7	42.4	10.9	NS
Lumbar ROM[b] (°)[22]	66.8	14.3	68.3	11.3	NS
Finger-floor test (cm)[19]	23.5	17.2	19.5	16.6	NS
Modified Schober test (cm)[19]	6.6	1.5	6.6	1.3	NS
Pain (mm)[c]	41.3	28.2	44.5	28.8	NS
Pain behavior[d,31]	2.8	1.7	3.3	2.4	NS

[a]NS=not significantly different between activity and control groups, *t* test.

[b]ROM=range of motion.

[c]Measured with 100-mm visual analogue scale.

[d]Maximum number of patients=10.

obliged to speak Swedish. Interpreters and properly translated forms for each native language were available.

Inclusion Criteria

All blue-collar workers employed at all divisions of the Volvo Company in Göteborg (inclusion criterion 1) and sick-listed for 6 weeks because of any diagnosis of LBP (inclusion criterion 2) were consecutively referred to the study during a 2½-year period. Only those patients who had no sick leave because of any diagnoses of LBP during a period of 12 weeks prior to the current sick-listing episode of LBP were included (inclusion criterion 3) (Fig. 1). Sick leave attributable to any diagnoses prior to this 12-week period was not considered. The patients were informed by mail of the design of the study before the study was conducted. Patients were included irrespective of place of birth or difficulties in speaking or understanding the Swedish language.

All patients were examined by an orthopedic surgeon (CÖ) and psychosocially evaluated by a social worker (CE) before randomization. The orthopedic surgeon conducted a complete medical examination. The social worker performed a standardized psychosocial screening including social, family, and work factors. The orthopedic surgeon excluded 18% of the referred patients with LBP because of the presence of specific diagnoses such as computed tomographic-verified disk herniation with indication for operation, spondylolisthesis, stenosis, instability exceeding 4 mm on flexion/extension radiographs, previous back surgery, vertebral fractures, tumors, inflammatory diseases, pregnancy, defined medical or psychiatric diagnoses, and drug abuse (C Öhlund, I Lindström, C Eek, et al; unpublished research). Patients were not excluded because of psychosocial factors. All remaining patients still sick-listed with a nonspecific, mechanical LBP disability (inclusion criterion 4) were consecutively included in the randomization process (C Öhlund, I Lindström, C Eek, et al; unpublished research).

Randomization

The approximate frequency of sick leave because of LBP in Göteborg and at the Volvo Company could be estimated before the study.[4,15] The patient referral lasted for 2½ years. Low back pain disability is known to be influenced by various factors. We believed that stratification for factors influencing LBP disability would probably create groups that would be too small or prolong the study too many years. For that reason, no prestratification was made. After 8 weeks of sick-listing, all referred patients with nonspecific, mechanical LBP disability were randomly assigned to either the activity group or the control group.

Table 2. *Percentage of Shift Workers, Job-Rotation Workers, and Workers with Monotonous Work, Sitting Work Postures, Forward-Bending Work Postures, Twisting Work Postures, and Lifting Demands at Work*

	Activity Group (n=49)[a]	Control Group (n=49)[b]	P[c]
Shift work	60%	53%	NS
Job rotation	41%	31%	NS
Monotonous work	39%	49%	NS
Sitting	55%	53%	NS
Forward bending	90%	90%	NS
Standing and twisting	92%	88%	NS
Lifting	69%	69%	NS

[a]Two patients in the activity group (n=51) were excluded from the analysis because they did not complete the 1-year follow-up examination.

[b]Three patients in the control group (n=52) were excluded from the analysis because they did not complete the 1-year follow-up examination.

[c]Not significantly different between activity and control groups, *t* test.

There were no significant differences between groups for the factors of age, lumbar range of motion, finger-floor test results, modified Schober's test results, pain, or pain behavior (Tab. 1). In our study, we did not assess the reliability of the widely used measurements. Patients in both groups were blue-collar workers with various physically demanding jobs from all divisions of the company, which produces cars and trucks. The number of shift workers, job-rotation workers, workers with monotonous work routines, workers with sitting work postures, workers with forward-bending work postures, workers with standing and twisting work postures, and workers with jobs with lifting demands did not differ significantly (t test) between the activity and control groups (Tab. 2).

All patients, both in the activity group and in the control group, were continuously and traditionally cared for by their regular physicians, not by the orthopedic surgeon in the study, before, during, and after the intervention. The sick-listing forms for the patients in both groups were completed by their regular physicians. Return to work was at the judgment of each patient's regular physician. The physicians who were responsible for the patients in the activity group were informed by the physical therapist (IL) of their patients' progress. Twenty-nine percent of the patients in the activity group and 28% of the patients in the control group were treated by a company health care physician. After the prerandomization examination, the patients in the control group were given the traditional care recommended by their physicians. Traditional care could include sick-listing with rest, analgesics, available physical therapy, and so forth (AL Nachemson, C Bengtsson; personal communication). The patients in the control group were not given any placebo care after the prerandomization examination, except for during the 1-year follow-up examination. The patients in the control group were not prevented from getting information from the patients in the graded activity program. All physicians of patients assigned to the activity group agreed for their patients to participate in the graded activity program, under the guidance of the physical therapist.

Sick Leave

Sweden's social insurance program is governed by laws enacted by Parliament and is administered by the National Social Insurance Board and by regional Social Insurance Offices. Three quarters of the cost of this program is financed by employers' contributions, and one quarter of the cost is financed by various taxes (eg, income tax, value-added tax). Everybody who lives in Sweden and has reached the age of 16 years is registered with a Social Insurance Office. Employees who are absent from work because of illness receive a sickness allowance, which is 90% of their annual income. People who are prevented from working or who must stop working because of illness or disability are entitled to receive a disability pension. Employees, upon reaching the age of 65 years, are eligible for a retirement pension. The Social Insurance Office also pays part of the cost when a person visits a physician, a physical therapist, or another health care professional, and most of the cost of any medicine prescribed. Patients' costs vary depending on the agreements between the health care professionals and the National Social Insurance Board as well as the laws enacted by the Parliament of Sweden.

In this study, records of the amount of sick leave taken over a 3-year period (ie, 1 year before intervention, the intervention year, and 1 year after the intervention year) were obtained from each patient's Social Insurance Office (Fig. 1). (Return to work was the end point of treatment. Patients returned to work, on average, after 10 weeks and were encouraged to return for a 1-year follow-up examination. Although no intervention was administered between the patient's return to work and the 1-year follow-up examination, records of the amount of sick leave taken were maintained during this period.)

Evaluation Procedure

The patients in the control group underwent the same initial examination by the orthopedic surgeon and the social worker as the patients in the activity group. The physical therapist initially evaluated only the patients who were assigned to the activity group. The patients in the control group did not meet with the physical therapist in the graded activity program until the 1-year follow-up examination in order not to contaminate the study. The patients in both groups were given a standardized examination and evaluated at a 1-year follow-up by the orthopaedic surgeon, the social worker, and the physical therapist. Ninety-six percent of the patients in the activity group and 94% of the patients in the control group attended the 1-year follow-up examination. Sick-leave data for all patients, however, were collected for a second follow-up year via the Social Insurance Offices (Fig. 1). The investigators were blind to the sick-leave data until the conclusion of the study.

Various outcome measures have been used to assess the effects of therapy on back pain.[1–3,5–20] Among the instruments used are impairment measures (eg, pain scales, measures of range of motion [ROM] and muscle strength), disability measures (eg, subjective disability ratings scales), and handicap measures (eg, return to work). Handicap measures are easy to implement, and the outcomes they measure have clear economic implications. These measures are often criticized, however, because they do not provide an indication of tissue recovery and impairment. These measures are also questioned because of their dependence on work availability and because of possible skewing of results through nonmedical co-interventions. Despite these drawbacks, we selected return to work as our primary outcome measure, mainly because these data are readily available from the Social Insurance Offices and constitute relatively hard end points (ie, patients either did return to work or did not return to work) with high reliability (Fig. 1). All patients in both

groups resumed their original jobs upon their return to work.

The Graded Activity Program

The purposes of the graded activity program were to restore occupational function and to facilitate return to work in a well-defined sample population (activity group) of patients with subacute LBP who were sick-listed for 8 weeks. Return to the previous nonmodified work place as soon as possible was the goal of the graded activity program. No ergonomic or other changes in the work situation were included in the graded activity program. The patients were not obliged to stay in the graded activity program for a specific number of weeks, and they were continuously encouraged to return to work. The graded activity program, which was conducted by a physical therapist, consisted of four main parts: (1) measurements of functional capacity; (2) a work-place visit; (3) back school education; and (4) an individual, submaximal, gradually increased exercise program, with an operant-conditioning behavioral approach, based on the results of the tests and the demands from the patient's work.

Functional capacity testing. The evaluation of the general condition of each patient's lower back and of his or her functional capacity was performed after randomization. The purpose of the initial measurements of individual functional capacity was to set a baseline for the individually graded exercise program, not to search for a specific diagnosis. The results of the individual functional capacity testing were used for positive reinforcement of the patient's gained function during the individually graded exercise program. The functional capacity tests measured the patient's mobility, strength, and fitness and took about 1 hour to complete. Measurements of functional capacity were also obtained at the 1-year follow-up examination of the patients in both groups (I Lindström, C Öhlund, C Eek, et al; unpublished research).

Forward bending was measured by the finger-floor test and the modified Schober test.[19] Backward bending was measured according to the procedure of Frost et al.[24] The lumbar and thoracic spinal ROMs in forward-backward bending were measured with a kyphometer, as described by Debrunner.[22] Lateral bending was measured according to the procedure of Frost et al.[21] Active leg raising was measured with the patient lying supine on the plinth and lifting one leg, using a predrawn wall goniometer. Spinal rotation was measured with the patient in a sitting position using a procedure modified from that of Mellin.[23] The ability to walk, to perform deep knee bends unilaterally and bilaterally, to climb onto a 25-cm-high stool and jump from the stool, to squat, and to stand on tiptoe with elevated arms was tested. Pulling and pushing were tested with a vehicle loaded with 100 kg of weights.

Abdominal muscle endurance time was measured (in seconds) with a stopwatch with the patient in a partial sit-up position using a procedure modified after the procedures of McQuade et al[18] and Biering-Sörensen.[19] Back muscle endurance time was also measured (in seconds) with a stopwatch using a procedure modified after those of McQuade et al[18] and Biering-Sörensen.[19] The patient's pulling-down capacity (in kilograms), with the arm in 90 degrees of elevation, was tested unilaterally and bilaterally with a wall-attached dynamometer. Lifting-to-tolerance capacity was tested with a simple box-lifting test.[24,25] A work test was performed on an electronic stationary bicycle with a fitness computer, according to the procedure described by Åstrand.[26] We did not determine the reliability of the measurements obtained in our study, but these measures are currently in widespread clinical use.

The measurements of pain, pain behavior, and disability in the activity group were initially obtained to set a baseline in the individually graded activity program and to be used for positive reinforcement of each patient's gained function. The measurements were also obtained at the 1-year follow-up examination of the patients in both groups. The perceived pain was measured with a category scale with ratio properties developed by Borg and colleagues.[27,28] Pain behavior was measured with the 10-item University of Alabama at Birmingham (UAB) Pain Behavior Scale developed by Richards.[29,31] Disability was measured with the subjective disability index.[20,32]

Work-place visit. Each patient's physical work demands were investigated in order to develop the individually graded exercise program, which was based on individual capacity and individual physical work demands. The patient, the physical therapist, and the supervisor together made a work-place visit, lasting about 1 hour, before constructing the individually graded exercise program. The purposes of the work-place visit were (1) to give the patient an opportunity to show his or her work situation, (2) to enable the supervisor to become actively involved in the rehabilitation process, and (3) to give the physical therapist an overview of the patient's work demands.

The physical therapist assessed each patient's physical work demands using a procedure for observing working postures and work performance (I Lindström, C Öhlund, C Eek, et al; unpublished research). The work demands were observed in terms of requirements for standing, standing and twisting, walking, sitting, sitting and twisting, lying, lying and twisting, kneeling, squatting, forward bending, backward bending, working with the arms above the shoulders, working with the hands above the shoulders, and working with the hands and arms without support. The work demands observed were modified after a validated questionnaire designed by Kilbom and colleagues.[33]

Education of patients using Swedish Back School principles. The physical therapist, at one visit lasting about 1 hour, taught the patients individually the main content of the Swedish Back School, de-

scribed in detail by Bergquist-Ullman.[15] The back school education included details of basic anatomy, functions of the muscles, functions of the back, and LBP disability treatments. The body's natural capacity for healing was emphasized. The slides of the ergonomic examples were obtained from the Volvo Company. The choice of slides was based on the operant-conditioning behavioral approach (ie, only positive reinforcing information was included). The included information was based on ability, not on LBP disability. At the work place, observed individual working postures and working techniques were discussed in terms of biomechanical load. The advantages of physical activity and the damaging effects of immobilization on muscles, tendons, joints, and disks were emphasized.[16–19,26,34,35] The content was based on current scientific knowledge.[6]

Individually graded exercise program with a behavioral therapy approach. *Pain* is defined by the International Association for the Study of Pain[36] as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Fordyce[37] pointed out that pain itself is not a disease; it is a symptom. Pain behavior should be understood to be a social communication, the meaning of which remains to be discovered in the individual case.[29,30,37] It should be recognized that we often use the language of pain to communicate suffering. Pain behavior can automatically come under the control of learning.[37] Learning is characterized by a change of behavior and will occur if conditions are favorable. One of the most effective ways to change behavior is to change the consequences that immediately follow the behavior. A behavior or action that is immediately and systematically followed by something pleasant (positive reinforcement) will tend to be increased or strengthened. If the consequences that follow the behavior are not pleasant or favorable, the behavior will probably weaken or cease. This process is called *operant conditioning*.[37]

The individually graded exercise program was set up using the operant-conditioning, or contingency-management, format first reported by Fordyce et al[38] and described in more detail by Fordyce.[37,39] As pertains to exercises, the essentials of the operant-conditioning approach are to develop an individually graded exercise program to teach the patient that it is safe to move while also increasing his or her activity level. Exercises are selected. A small number of initial baseline trials are carried out in which the patient exercises to the limit of tolerance. Detailed performance records are kept during these baseline trials. The therapist then sets quotas of exercises to be performed in each trial based on the patient's baseline levels. Initial quotas are slightly lower than the baseline levels (eg, 75% of baseline levels), but are increased systematically. The task for the patient has now shifted from exercising to tolerance (ie, rest or time out from exercising is pain-behavior contingent) to exercising to quota (ie, rest is contingent on performing a certain amount of exercise) (Fig. 2). Quotas are never to be exceeded. Increment rates are determined based on the therapist's judgment, but in all cases they should be determined prior to starting the quota phase of the individually graded exercise program.

The physical therapist selected the individual exercises to be included in each patient's program according to tested individual functional capacity and observed individual physical work demands. The individually graded exercise program included endurance and strength training, lifting exercises, walking, jogging, swimming, group gymnastic exercises, and fitness exercises on a bicycle ergometer. The patient's earlier experience was also considered when choosing suitable individually graded exercises. Swimming, for example, was included if the patient had earlier swimming practice. The individually graded exercise program included exercises presumed to benefit patients with LBP, such as

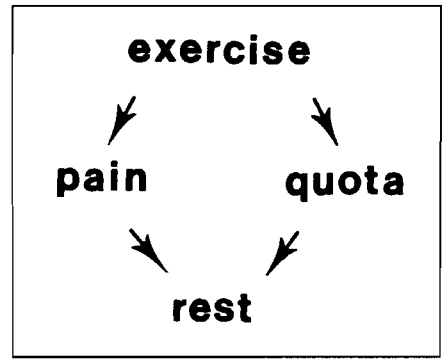

Figure 2. *Fordyce's model of exercise to quota, not to pain.[38] The individually graded exercises were set to quota (ie, the patients did not stop the exercise because of pain or other tolerance factors, as the quota was always set below tolerance). The graded exercises set to a quota were followed by something pleasant (ie, rest) rather than by something unpleasant (ie, pain).*

abdominal and back muscle exercises[16–19,34] and cardiovascular fitness exercises.[18,26,34,35] Each patient performed more than one kind of exercise before his or her return to work. The individually graded exercise program used only simple equipment and facilities such as dumbbells, a stationary bicycle, an indoor pool, and a gymnasium.

According to individual functional capacity and individual physical work demands, the physical therapist selected different kinds of exercises for the patients in the activity group (eg, 87% and 91% of the male and female patients, respectively, performed abdominal and back muscle exercises; 71% and 91% of the male and female patients, respectively, performed leg muscle exercises; 66% and 91% of the male and female patients, respectively, performed arm muscle exercises; 53% and 36% of the male and female patients, respectively, performed lifting exercises; 8% and 82% of the male and female patients, respectively, performed group gymnastic exercises; 21% and 27% of the male and female patients, respectively, performed jogging exercises; 74% and 73% of the male and female patients, respectively, performed swimming exercises; 24% and 36% of the male and female pa-

tients, respectively, performed walking exercises; and so forth).

Each patient in the activity group performed more than one kind of exercise before his or her return to work (eg, 88% performed abdominal and back muscle exercises; 71% performed abdominal and back muscle exercises combined with bicycle ergometer exercises; 60% performed abdominal, back, arm, and leg muscle exercises combined with bicycle ergometer exercises; 20% performed abdominal and back exercises combined with jogging exercises; and so forth).

Each individually graded exercise was first demonstrated by the physical therapist. Examples of exercise performance and quota setting are given in the Appendix. Quotas were set for the frequencies, loads, laps, repetitions, and endurance time for each exercise. How, when, and where to perform the exercises were individually prescribed in detail. Each patient in the activity group participated in the individually graded exercise program on an outpatient basis, in the recreation department of the company, 3 days a week until his or her return to work. No home exercises were required.

The physical therapist gave continuous positive reinforcement for performed quotas and increased functional capacity.[38] The therapist observed and recorded each patient's complaints of pain or disability and displays of pain behavior, but made no attempt to change the program in response to such displays.[38] The individually graded exercise program was extended by adding individually graded exercises set to quotas. The individually graded exercise program was initially performed with the physical therapist continuously present. Less presence and less attention by the physical therapist were also increased quotas. The individually graded exercise program gradually moved toward self-training sessions, though the patient's performance was continuously checked and recorded by the physical therapist. The patient's return to his or her previous nonmodified work place was the goal of the individually graded exercise program.

Data Analysis

The prerandomization recordings of age, lumbar ROM, finger-floor test results, modified Schober's test results, pain, and pain behavior in the activity and control groups were compared with *t* tests in the Statistical Analysis System (SAS) program for computers.*[40] The recordings of shift work, job rotation, monotonous work, sitting work postures, forward-bending work postures, standing and twisting work postures, and lifting demands in the both groups were also compared with *t* tests in the SAS program for computers.

The log likelihood ratio test was used in the Lifetest procedure of the SAS program for computers.[40] The Lifetest procedure can be used with data that are right-censored to compute nonparametric estimates of the survival distribution. The log likelihood ratio test was used to compare the rate of return to work between the activity group and the control group. The sick-listing days between the randomization and the day of return to work for all patients were included in the data analysis. The cutoff of rate of return to work was set to the 1-year follow-up examination (at 2 in Fig. 1). Three activity group patients (2 male, 1 female) and 5 control group patients (4 male, 1 female) were censored, as they did not return to work before the 1-year follow-up examination (Fig. 1). Comparison within gender was also performed with the log likelihood ratio test.

The activity group (n=51) and the control group (n=52) were compared with respect to the rate of return to work during the intervention year (from 1 to 2 in Fig. 1) and the sick-leave recordings during the year after the intervention year (from 2 to 3 in Fig. 1). The influence of the time recovery effect was assumed to be controlled for in that way, as patients with LBP will recover over time.[2]

The number of sick-listing days during the second follow-up year (from 2 to 3 in Fig. 1) for all patients in the activity and control groups was compared with a *t* test using the SAS program for computers (Fig. 1). Comparison within gender was also performed with a *t* test.

The number of patients in the activity and control groups with and without recurrences for all diagnoses during the second follow-up year was analyzed with Fisher's Exact Probability Test using the SAS program.

For the activity group patients who participated in the graded activity program (n=49), the association between the rate of return to work and the number of appointments with the physical therapist as well as the number of self-training sessions before return to work were analyzed with the Spearman rank-order correlation *(r)* using the SAS program.

Results

Exercises

Fifty-five percent of the patients who participated in the graded activity program (n=49) had 5 or fewer appointments with the physical therapist before their return to work, 75% of the patients had 14 or fewer appointments with the physical therapist before return to work, and 90% of the patients had 25 or fewer appointments with the physical therapist before return to work. The median number of appointments with the physical therapist before return to work was 5 for all patients. Four male patients and 1 female patient had more than 25 appointments with the physical therapist before return to work. The appointments with the physical therapist included functional testing, a work-place visit, back school education, construction of the individ-

*SAS Institute Inc, PO Box 8000, Cary, NC 27511.

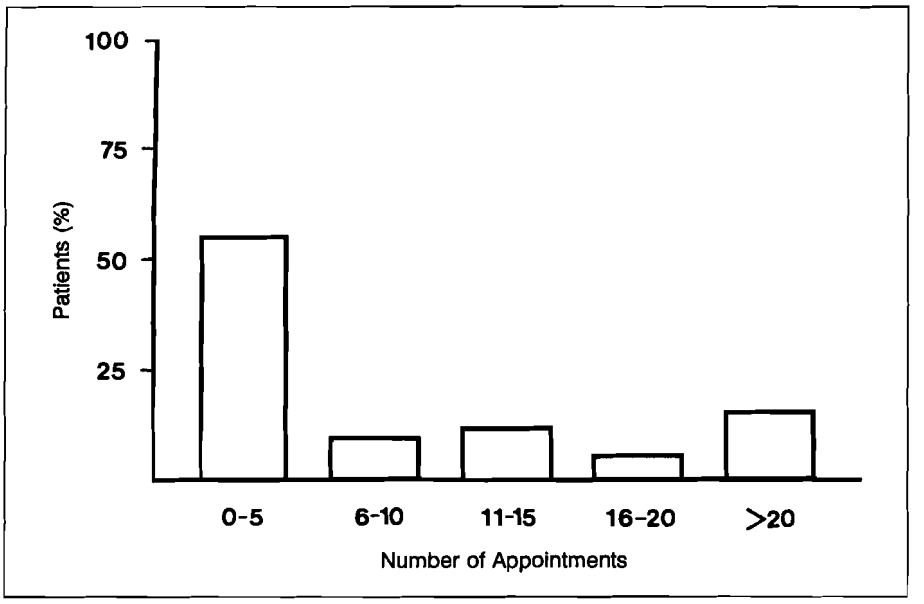

Figure 3. *Percentage of patients and number of appointments with the physical therapist in the activity group (n=49) before return to work, which was the end point of the intervention.*

ually graded exercise program, and individual treatments. The proportion of patients who participated in the graded activity program and the number of appointments with the physical therapist before return to work are shown in Figure 3. The patients had, on average, 10.7 appointments with the physical therapist before return to work (SD=12.3) (male patients: average=10.4, SD=12.2; female patients: average=11.7, SD=13.2). No significant difference was found between genders.

Fifty-nine percent of the activity group patients participated in an average of 9.7 self-training sessions before they returned to work (SD=17.7) (male patients: average=9.6, SD=19.5; female patients: average=9.9, SD=10.2). The median for all patients in the activity group was 3 sessions. Among the patients who carried out self-training sessions, the median was 8 sessions. No significant difference was found between genders.

On the day of randomization, all patients were still sick-listed. Two patients refused to participate in the graded activity program. Between the randomization day and the day for the first appointment with the physical therapist, four patients had returned to work. All patients except four performed individually graded exercise programs before return to work. These four patients each had two appointments with the physical therapist and returned to work 6, 16, 23, and 28 days, respectively, after randomization.

Rate of Return to Work

The log likelihood ratio test showed that patients in the activity group returned to work earlier (χ^2=4.7, P=.03) than did patients in the control group (Fig. 4). The log likelihood ratio test also showed that male patients in the activity group returned to work earlier (χ^2=6.1, P=.01) than did male patients in the control group. No difference was found between groups for the female patients.

Fifty-nine percent of the patients in the activity group had returned to work within 6 weeks and 80% within 12 weeks after randomization. In the control group, 40% of the patients returned to work within 6 weeks and 58% within 12 weeks. The average time before return to work was 10.0 weeks (SD=12.7) in the activity group (male patients: average=9.7, SD=12.9; female patients: average=11.0,

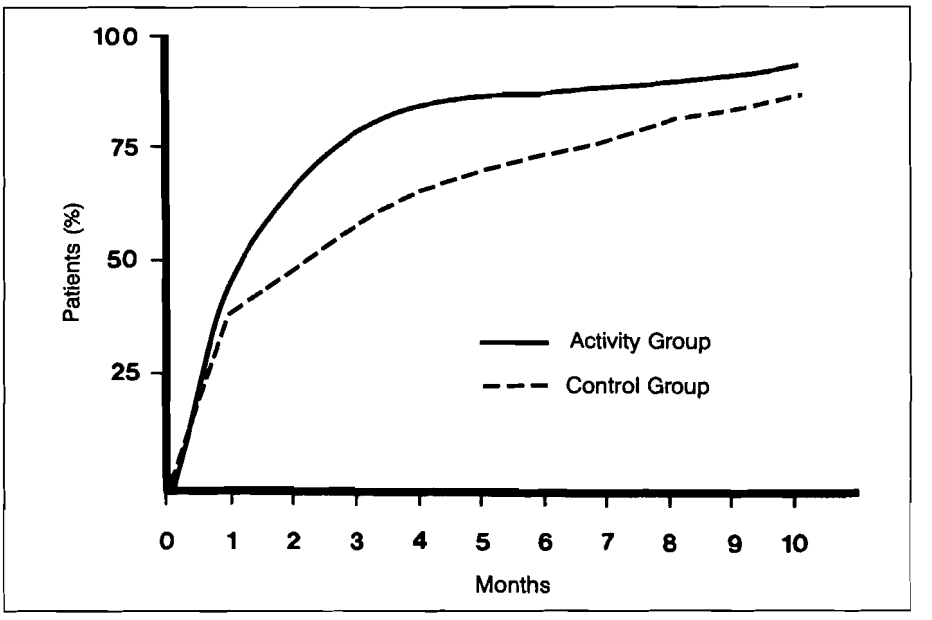

Figure 4. *Rate of return to work in the activity group (n=51) and in the control group (n=52). The comparison included the number of sick-listing days before return to work (ie, between randomization and the 1-year follow-up examination). The rate of return to work was significantly faster in the activity group than in the control group (log likelihood ratio test χ^2=4.7, P=.03).*

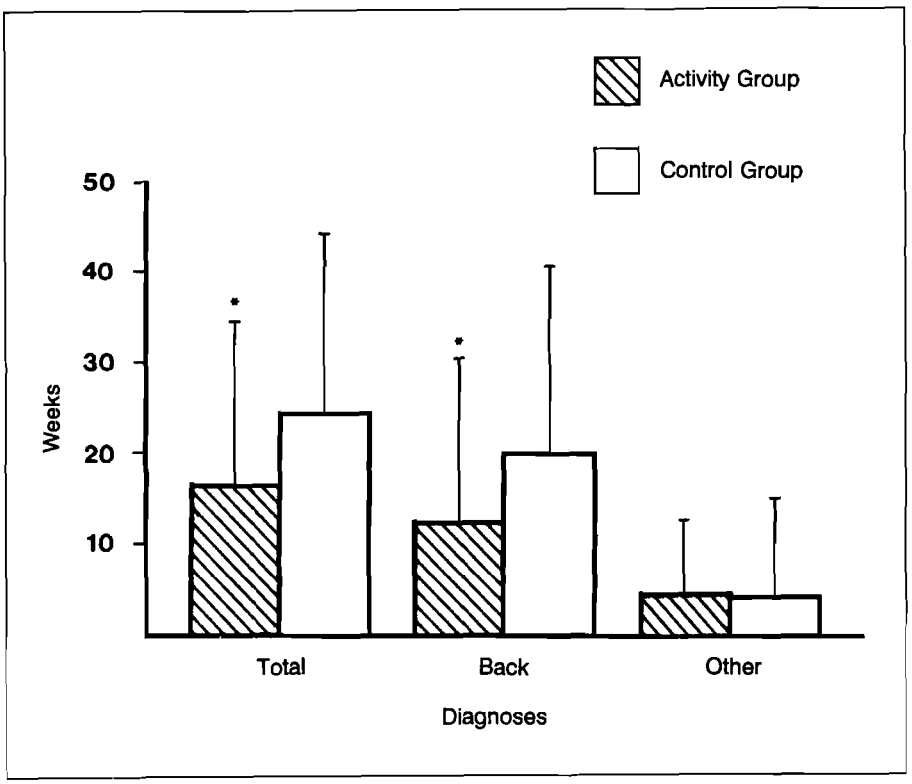

Figure 5. *Total sick leave and separate low back pain sick leave as well as other sick leave (mean and standard deviation) during the second follow-up year in the activity group (n=51) and in the control group (n=52). Asterisks represent significance between groups.*

SD=12.4). Their median time before return to work was 35 days. In the control group, the average time before return to work was 15.1 weeks (SD=15.6) (male patients: average=16.7, SD=16.3; female patients: average=12.6, SD=14.4). Their median time before return to work was 61 days.

Two-Year Follow-up

The average duration of sick leave attributable to LBP during the second follow-up year (Fig. 5) was 12.1 weeks (SD=18.4) in the activity group (male patients: average=11.0, SD=19.1; female patients: average=15.9, SD=16.4) and 19.6 weeks (SD=20.7) in the control group (male patients: average=21.6, SD=20.3; female patients: average=16.6, SD=21.7). The difference between groups was significant (t test, P=.05). The difference between groups for the male patients was significant (t test, P=.03). No significant difference between groups was found for the female patients. The average duration of sick leave for other diagnoses during the second follow-up year (Fig. 5) was 4.4 weeks (SD=7.9) in the activity group and 4.7 weeks (SD=10.6) in the control group (t test, P=.9).

The average total duration of sick leave during the second follow-up year (Fig. 5) was 16.6 weeks (SD=18.4) in the activity group (male patients: average=15.1, SD=19.5; female patients: average=21.1, SD=13.9) and 24.3 weeks (SD=19.7) in the control group (male patients: average=27.2, SD=19.2; female patients: average=19.6, SD=20.1). The difference between groups was significant (t test, P=.04). The difference between groups for the male patients was significant (t test, P=.01). No significant difference between groups (t test) was found for the female patients.

Forty-two percent of the patients in the activity group and 21% of the patients in the control group had no recurrences of LBP during the second follow-up year. The proportions of patients with recurrences of LBP were significantly lower (Fisher Exact Probability Test: lower tail=.9996, upper tail=.001) in the activity group (58%) than in the control group (79%).

Four patients (all male) in the activity group and 11 patients in the control group (8 male, 3 female) were sick-listed during the whole second follow-up year. Five patients (all male) of the 103 randomly assigned patients were granted a permanent disability pension by the Social Insurance Offices during the 2-year follow-up period. Four patients in the control group (aged 42, 50, 50, and 60 years, respectively) and 1 patient in the activity group (aged 58 years) received a permanent disability pension.

The two patients refusing graded activity returned to work after 15 and 29 days, respectively, but did not attend the 1-year follow-up examination. In the control group, 3 patients did not attend the 1-year follow-up examination. Two patients returned to work after 13 and 59 days, respectively. The third patient did not return to work and received a permanent disability pension. Thus, 96% of the randomly assigned patients attended the 1-year follow-up examination.

The number of appointments with the physical therapist was positively correlated to the rate of return to work (Spearman r=.82, P=.0001). The number of self-training sessions was also positively correlated to the rate of return to work (Spearman r=.52, P=.0001). The number of appointments with the physical therapist (Spearman r=.83, P=.0001) and the number of self-training sessions (Spearman r=.45, P=.005) were positively correlated to the rate of return to work. The number of appointments with the physical therapist (Spearman r=.83, P=.002) and number of self-training sessions (Spearman r=.67, P=.02) were also positively correlated to the rate of return to work for the female patients.

Discussion

The graded activity program was demonstrated to be effective for the patients with subacute, nonspecific, mechanical LBP in this study. The main outcome variables in this randomized study were return to work and sick leave during the second follow-up year. The patients in the activity group returned to work earlier and had less sick leave during the second follow-up year than did the patients in the control group. The patients in the activity group, on average, returned to work 5.1 weeks earlier than did the patients in the control group. The male patients in the activity group, on average, returned to work 7 weeks earlier than did the male patients in the control group. Other comprehensive programs for patients with LBP have given similar results, but under less well-controlled conditions.[4,7–14] Spitzer,[6] in 1987, reported that no randomized controlled studies had demonstrated the usefulness of any treatment for patients with activity-related spinal disorders after more than 8 weeks of sick leave.

The examination by the orthopedic surgeon and the psychosocial evaluation by the social worker before entering the graded activity program were intended to contribute to the efficacy of the graded activity program. These examinations were intended to make the patients feel confident. It should be noted, however, that the patients in the control group also had this examination, even though they did not take part in the graded activity program.

The content of the Swedish Back School puts LBP in a scientific context for the patient.[15,41] The patients seemed glad to learn that they were not to be blamed for having LBP. The back school information was useful for planning the exercise program, as the patients knew that activity, not rest, would help them to regain function.

The aim of the operant-conditioning method is to teach the patients that it is safe to move while restoring function.[37] The exercise program did not use "work-hardening" or intensive exercises. The functional capacity tests in the graded activity program were performed not to search for a specific diagnosis, but to measure the present level of functional capacity and hence set a baseline for the individually graded exercise program. Each patient's exercise level was lower than his or her maximal capacity.[37] The patients knew their performed functional capacities because of the baseline trials.[37]

We believe the pain and disability reporting using preprinted scales made the patients motivated for the graded activity program by showing that the therapists were aware of their suffering. We used the patients' functional capacity, not the patients' pain, to govern the individually graded exercises and the rate of increase of intensity. The individually graded exercises did not increase pain, as indicated by the patients' continuing to achieve increasing quotas. The patients were not competing with each other, only with themselves, as all exercises were individually set to quota depending on each patient's current functional capacity. We believe the patients learned that they could move without increased pain and thus became more confident when performing the prescribed exercises. The patients realized that it is not necessary to be totally free from pain to perform exercises. The operant-conditioning behavioral method was a useful approach. Deliberate neglect of complaints of pain and pain behavior was useful in the treatment of the patients. The complaints were always considered real, but did not govern the treatment. Fordyce et al[29] reported that exercise and pain complaints were negatively correlated in patients with chronic pain. The more the patients did, the fewer pain behaviors they displayed.

All patients were able to perform some kind of exercises, as they were individually set depending on the individual functional capacity. The performed and increased quotas were always positively reinforced by the physical therapist.

The significant positive correlation among the number of appointments with the physical therapist, the number of self-training sessions, and the rate of return to work was not surprising, as the end point of the graded activity program was return to work. The graded activity program was ended for each patient when he or she had worked full-time for 4 weeks. The more sick-listing days the patients had before return to work, the more opportunities they had for appointments with the physical therapist and the more opportunities they had for performing self-training sessions.

The difference in numbers between genders in the two groups can only be explained by the randomization process itself, as no stratification was made for gender. The comparisons between the female groups are less generalizable, as the groups were very small. The results for the female patients are limited because of the small number of patients in each group. The proportion of female patients in the sample, however, was equal to the proportion of female employees in the company. The available jobs in the company, as in many other companies, are not primarily designed for women. This may partly explain the lower success rates for the female patients than for the male patients. The lower rate of success of adding the graded activity program to traditional care in the female patients in the activity group, however, can be explained by the fact that traditional care is typically adequate for female patients. Most explanations for the effects in female patients are assumptions, as the number of female patients in both groups was too small to allow general conclusions.

The sample comprised proportionately more immigrants than the company's population of immigrants. The large immigrant proportion might be explained by other work situations, sick-leave habits, and so forth. Most of the immigrants in this study had been employed more than 10 years. In Sweden, immigrants must have a valid resident's visa to obtain a work permit. Unlike many LBP studies, immi-

grants were not excluded from this study because of their inability to speak and understand the language. Because of the large proportion of immigrants, the results of the study could not be separated according to nonimmigrant and immigrant status and still be generalizable. The graded activity program was effective, however, despite no exclusion of patients because of place of birth or difficulties in speaking or understanding the Swedish language. This finding should make the results of this graded activity program more generalizable for an industrial population anywhere in the industrialized world than the results of many other studies in which such patients have been excluded.

The individually graded exercise program did not use any exceptional or expensive equipment. Thus, graded activity programs can be set up without extremely expensive investments.

The patients in the graded activity program did not need a lot of treatment sessions to regain occupational function and return to work. Fewer than 50% of the patients needed more than five appointments with the physical therapist before return to work. In Sweden, the most common number of physical therapy appointments prescribed is 10 sessions.

The graded activity program led to clear insurance savings. Less sick-leave compensation had to be paid by the Social Insurance Offices, and fewer physical therapy appointments (which, in Sweden, are also paid for by the Social Insurance Offices) were needed. The graded activity program had other economic benefits, as it was run without expensive equipment, with only one physical therapist in charge of the program and on an outpatient basis at a recreation department, and the patients in the activity group had a higher rate of return to work than did the patients in the control group. The economic savings were continued for at least 2 years after the intervention, as the patients in the activity group were less often sick-listed during the second follow-up year. The activity group patients' quality of life also improved, as they learned that it is safe to move while regaining function and that they could return to their normal life with less sick leave. We assume that this type of graded activity program will save money for the health care system and for society as well as improve the quality of life for each patient.

Summary

The patients with subacute, nonspecific, mechanical LBP who participated in the graded activity program regained occupational function faster than did the patients in the control

Appendix. *Exercise Performance and Quota Setting in the Activity Group*

BACK MUSCLES

Extension exercises were performed with the patient lying prone, arms along the trunk. The trunk was raised until there was no contact between the male patients' chest and the support surface or until there was no pressure on the breasts of the female patients; this amount of back muscle extension was never to be exceeded. The exercises were increased by adding arm or leg support in different combinations when performing back muscle extension. One exercise was to hold that upper position 75% of the tested endurance time. For example, if the tested endurance time was 16 seconds, then the quota of exercise endurance time was 12 seconds. If the tested frequency was 12 repetitions, then the quota of exercise frequency was 9. Increased quota could mean increased number of endurance seconds or increased number of repetitions.

ABDOMINAL MUSCLES

Exercises were performed with the patient lying supine, knees flexed, feet unsupported, hands stretched toward the knees, and trunk curled until the angulus inferior of the scapula had no support. Increase of abdominal muscle exercises were activated by repositioning the arms when performing the exercises. The quota was set in the same way as for back muscle exercises.

FITNESS EXERCISES

The exercise on a stationary bicycle was set to quota by recording the number of minutes and the load on the bicycle. If the test showed a capacity of 12 minutes of 150 W, the quota could be 5 minutes at 50 W followed by 9 minutes at 100 W and then 5 minutes at 50 W. Increased quota could mean either increased number of minutes or increased load. Fitness exercise could also include stepping up and down on a stool, climbing stairs, swimming backstroke, walking, or jogging.

SWIMMING BACKSTROKE

The patient swam 8 laps backstroke in the initial trials. The quota for swimming backstroke was set at 6 laps. Increased quota meant increased number of laps or shorter time per lap.

LEG MUSCLES

Exercises were carried out standing and shifting the body weight between the legs while lifting the heels or bending the knees. Sitting in a chair or on the floor, unilateral lifting of one straight leg was also performed.

ARM MUSCLES

Exercises were carried out by lifting the arms in different directions while holding dumbbells. The arm exercises were performed lying prone, lying supine, sitting, or standing. Increase of arm exercises meant addition of heavier dumbbells or further lifting positions.

LIFTING

Exercises were carried out by lifting dumbbells in different directions while standing. Increase of lifting exercises meant addition of further directions or heavier dumbbells.

group, who were given only traditional care. The graded activity program significantly reduced long-term sick leave, especially in the male patients. The operant-conditioning method was useful in regaining occupational function. The patients in the graded activity program learned that it is safe to move while regaining function. Intensive exercises, "work-hardening" exercises, or expensive equipment were not necessary to regain occupational function.

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The Effect of Graded Activity on Patients with Subacute Low Back Pain: A Randomized Prospective Clinical Study with an Operant-Conditioning Behavioral Approach

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