

Multidisciplinary Rehabilitation for Subacute Low Back Pain: Graded Activity or Workplace Intervention or Both?

A Randomized Controlled Trial

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Study design. Population-based randomized controlled trial.

Objective. To assess the effectiveness of workplace intervention and graded activity, separately and combined, for multidisciplinary rehabilitation of low back pain (LBP).

Summary of Background Data. Effective components for multidisciplinary rehabilitation of LBP are not yet established.

Methods. Participants sick-listed 2 to 6 weeks due to nonspecific LBP were randomized to workplace intervention (n = 96) or usual care (n = 100). Workplace intervention consisted of workplace assessment, work modifications, and case management involving all stakeholders. Participants still sick-listed at 8 weeks were randomized for graded activity (n = 55) or usual care (n = 57). Graded activity comprised biweekly 1-hour exercise sessions based on operant-conditioning principles. Outcomes were lasting return to work, pain intensity and functional status, assessed at baseline, and at 12, 26, and 52 weeks after the start of sick leave.

Results. Time until return to work for workers with workplace intervention was 77 versus 104 days (median) for workers without this intervention ($P = 0.02$). Workplace intervention was effective on return to work (hazard ratio = 1.7; 95% CI, 1.2–2.3; $P = 0.002$). Graded activity had a negative effect on return to work (hazard ratio = 0.4; 95% CI, 0.3–0.6; $P < 0.001$) and functional status. Combined intervention had no effect.

Conclusion. Workplace intervention is advised for multidisciplinary rehabilitation of subacute LBP. Graded activity or combined intervention is not advised.

Key words: return to work, low back pain, effectiveness, graded activity, workplace intervention. **Spine 2007; 32:291–298**

Low back pain (LBP) is the most common and expensive musculoskeletal disorder in industrialized countries.¹ The 12-month prevalence in the general population has been estimated at 44%.² LBP is frequently associated with persistent or recurrent disability and absence from work.³ High costs are mainly due to sick leave and disability.⁴ Almost one fourth of workers with LBP reported sick leave in the past year in the Netherlands.² Therefore, from an individual and societal perspective, effective interventions for LBP are needed to prevent long-term disability and promote early and safe return to work.

In recent Cochrane reviews^{5,6} and in most clinical guidelines, multidisciplinary biopsychosocial rehabilitation programs are advocated for subacute and chronic LBP. However, according to these reviews, it remains unclear what the (cost)effective components in these multidisciplinary programs are. It is therefore concluded that high-quality randomized controlled trials (RCTs) are needed to assess the effectiveness of components separately and combined.

Objectives

In an RCT, Loisel *et al*⁷ found that workplace intervention, as a component in multidisciplinary rehabilitation, was effective on disability and return to work, that clinical intervention had no effect, and that the combination of both interventions had a (small) additional effect. To evaluate whether workplace intervention, clinical intervention, or both are more effective than usual care in another socio-cultural environment, we adjusted the Canadian interventions and study design to the Dutch socioeconomic context⁸ and replicated the Canadian study. The Dutch workplace intervention after 2 weeks of sick leave consisted of a workplace assessment, work modifications, and case management in which all major stakeholders in the return-to-work process participated: *i.e.*, the worker, the employer, the occupational physician (OP), and the worker's general practitioner (GP).

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The clinical intervention after 8 weeks comprised a graded activity program, *i.e.*, a gradually increasing exercise program based on a cognitive behavioral approach.

■ Methods

Study Design and Setting. This study comprised a single-blind pragmatic population based RCT, evaluating workplace intervention and/or graded activity aimed at return to work after LBP. Thirteen Dutch Occupational Health Services (OHS) and 16 physiotherapy centers for a total of 99 OPs, 25 ergonomists, and 47 physiotherapists (PT) participated in this study. The Medical Ethics Committee of VU University Medical Center approved the study design, protocols, procedures, and informed consent procedure, and all participants provided written informed consent. Detailed description of study design and setting is published elsewhere.⁸

Participants. The source population ($n =$ approximately 100,000) consisted of the worker's population of the participating OPs. It was judged by the researchers whether the workers met the inclusion criteria before the first visit to their OP. The inclusion criteria were: nonspecific LBP,⁸ full or partial sick leave due to nonspecific LBP lasting 2 to 6 weeks, age between 18 and 65 years, and able to give written informed consent and to complete written questionnaires in Dutch.

The worker's OP informed the researchers whether a subject should be excluded due to the following medical criteria: LBP due to specific causes; coexisting cardiovascular, psychiatric, or juridical contraindications; pregnancy; and sick leave due to LBP less than 1 month before the current episode of sick leave.

Treatment Allocation and Blinding. To reduce the risk of contamination, first randomization took place at the level of the OP, after prestratification by economic sector of the OP's worker population. The researcher (I.A.S.) and research assistant who collected the baseline data were blinded for the treatment allocation.⁸ Treatment allocation was made known by the OP to the worker after informed consent and completion of the first questionnaire. Second, workers who were still on sick leave after 8 weeks were randomized at the patient level for graded activity. An independent examiner (H.C.W.dV.) prepared the envelopes for randomization by coding them according to a list of random numbers. Data on return to work were derived from automated databases to prevent bias caused by a lack of blinding. Although blinding of self-reported outcome measurements during follow-up was not possible, there was no direct influence by the researchers or treating professionals because all questionnaires were mailed to the worker.

Interventions and Training. The Canadian interventions⁷ were adjusted to the Dutch socioeconomic context.⁸ In the Netherlands, workers sick-listed due to low back pain visit their OP. Usual medical care of OPs is according to the Dutch occupational guideline on LBP.⁹ In addition to care according to the Dutch occupational guideline on LBP, workplace intervention and/or graded activity was applied. The workplace intervention took place directly after inclusion. The workplace intervention consisted of a workplace assessment and work adjustments in which all major stakeholders in the return-to-work process participated: *i.e.*, the worker, the employer, the

Table 1. Content of Interventions

Usual care	The Dutch occupational guideline on low back pain (LBP) advises for nonspecific LBP ⁹
	Education about the good prognosis and the importance of keeping up or returning to normal activities
	Coping with low back pain, fear of movement, and a planning for the resumption of normal activities is discussed with the worker, if considered appropriate
	Advise to return to work within 2 weeks in the absence of further problems and, if necessary, temporary work adjustments regarding working hours or job content. A workplace visit by an occupational therapist or ergonomist is optional
	The general practitioner, or any other medical specialist, is consulted if curative treatment is considered inappropriate
Workplace intervention	The workplace intervention consisted of a worksite assessment and work adjustments, based on methods used in participatory ergonomics. ¹⁰ For each worker, a group was formed that included an ergonomist (process leader), the injured worker, the worker's supervisor, and possible other stakeholders. After observation of the worker's tasks by the ergonomist, obstacles for return to work were ranked independently by the worker and the supervisor. Following this, the ergonomist organized a meeting of the group of stakeholders to brainstorm and discuss about all possible solutions for the obstacles ranked highest. The aim was to achieve consensus regarding feasible solutions. Finally, a short communication form was exchanged between the OP and the worker's GP to prevent conflicting advises to the worker in the return-to-work process ¹¹
Graded activity	The intervention consisted of an individual, submaximal, gradually increasing exercise program with an operant-conditioning behavioral approach. The content of the program was tailor made and based on the findings from patient history, physical examination, functional capacity evaluation, demands from the patients' work, and the patients' expectations on time to return to work. The aim of this intervention was return to full own or equal work. During the program, an active role of the worker in return to work was promoted and the PT acted as a coach and supervisor, using a hands-off approach. ^{8,12} The entire program consisted of two 1-hour sessions a week, with 26 sessions maximally. The program stopped as soon as a lasting return to own or equal work had been established, according to an agreed individual schedule

OP, and the worker's GP.^{10,11} Graded activity took place at 8 weeks after the start of sick leave. Graded activity comprised a gradually increasing exercise program based on a operant-conditioning approach.¹² In Table 1 is more detailed information provided about the interventions.

The OPs randomized to the workplace intervention group, PTs and ergonomists received 3 training sessions of 1×4 and 2×2 hours. All training sessions consisted of theory, role playing, and feedback on the practiced skills. OPs not randomized to the workplace intervention group received one 2-hour training to apply the guideline only. We provided all professionals a treatment manual.

Outcome Measures and Prognostic Factors. Sick leave duration due to LBP was the primary outcome measure. Sick leave was defined in this study, following the Dutch social security laws, *i.e.*, duration of sick leave in calendar days from the first day of sick leave to full return to work in own or equal work, for at least 4 weeks without (partial or full) dropout. This implicates that for workers who returned to other or not lasting work during the entire follow-up, time to return to work was censored in survival analyses. In addition, the total duration of sick leave due to LBP (including all recurrences of sick leave

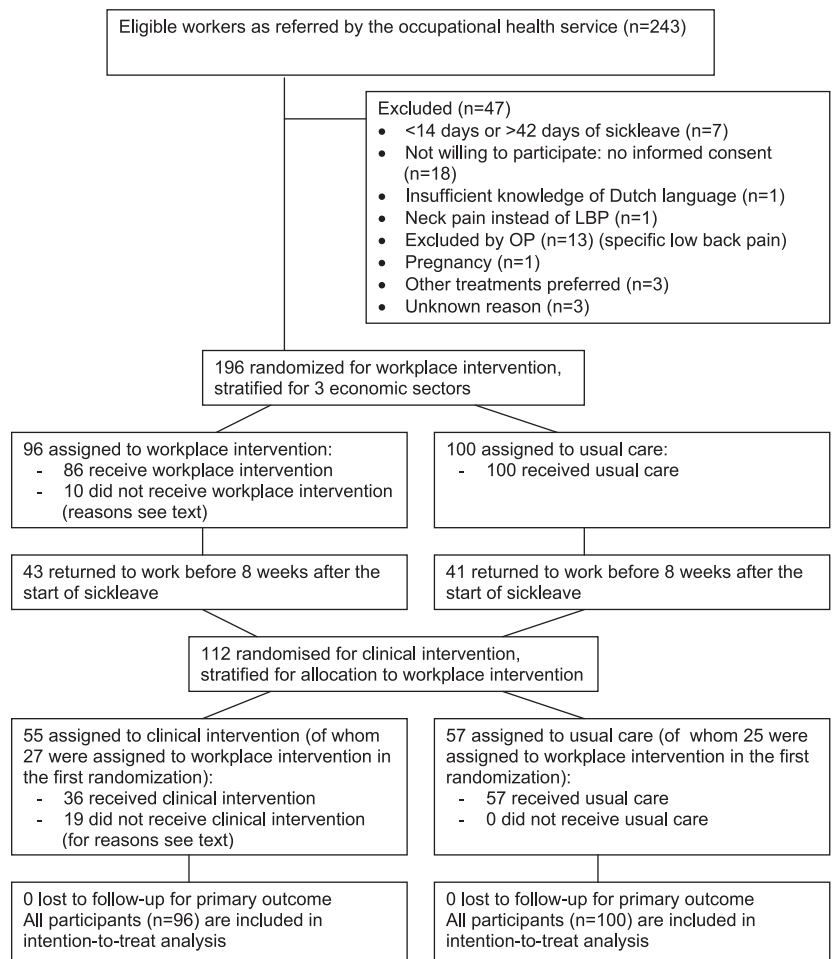


Figure 1. Flow diagram describing the progress of the workers through the phases of the trial.

episodes) was calculated for the entire 12-month follow-up period. Sick leave data were collected continuously during follow-up from automated databases. Functional status and pain were secondary outcome measures. Functional status of the worker was measured by the Roland-Morris Disability Questionnaire.^{13,14} An individual score could vary from 0 (no disability) to 24 (severe disability). Pain intensity was measured on a 10-point visual analogue scale ranging from 0 (no pain) to 10 (very severe pain).¹⁵ The secondary outcomes were assessed at baseline, and at 12, 26, and 52 weeks after the first day of sick leave. Finally, data were collected on prognostic factors for duration of sick leave.⁸

Power Calculation. To detect a 20% and 30% difference in return-to-work rate (full return to work) for the workplace and graded activity respectively, a sample size of 200 workers is needed.⁸ These differences can be detected with a power $(1 - \beta)$ of 80% at $\alpha = 0.05$.

Statistical Analyses. First, we studied baseline similarity. Second, intraclass correlation coefficients were estimated to check whether there was independency of observations between OPs. All analyses were conducted at the worker's level and according to the intention-to-treat principle. Third, survival analyses were used to investigate the intervention effect (hazard ratio of return-to-work rates between treatments). Time-dependent covariates in the multivariate models were used to adjust for the fact that treatment allocation for the workplace intervention

and graded activity took place at different moments. A prognostic factor was defined as a potential confounder when there was a $P < 0.10$ difference between groups in the baseline value of a prognostic variable or when it is a known prognostic factor in the literature.¹⁶ Consequently, a potential confounder was added manually and separately to the multiple regression model to check whether the $-2 \cdot \log$ likelihood of the model changed significantly when the factor was added. When the $-2 \cdot \log$ likelihood changed significantly ($P < 0.05$), the factor was entered into the final model.¹⁶ Interaction was tested between workplace intervention and graded activity, and between these interventions separately and all confounders at baseline or prognostic factors found in the literature.¹⁷ Finally, longitudinal random coefficient analyses were used to assess differences between treatment groups in improvement in the secondary outcome measures. The baseline value of the particular outcome variable was added to the model in order to correct for possible regression to the mean. Survival analyses, intraclass correlation coefficient, and random coefficient analyses were performed using the SPSS 10.0 software package (SPSS Inc.), STATA (version 7) and MLwiN (version 1.10), respectively.

■ Results

Patient Flow and Dropout

The flow of the workers in this study during the recruitment, inclusion, and the follow-up is presented in Figure 1.

Table 2. Prognostic Variables and Baseline Values of Outcome Measures

	Workers on Sick Leave >2 Weeks (n = 196): Workplace Intervention		Workers on Sick Leave >8 Weeks (n = 112): Graded Activity	
	Yes (n = 96)	No (n = 100)	Yes (n = 55)	No (n = 57)
Baseline characteristics				
Age (yr) [mean (SD)]	44.0 (8.6)*	41.2 (10.7)*	41.3 (9.2)	43.4 (8.3)
Gender (male/female)	51/45*	33/67*	19/36	26/31
Function				
Industrial	11	6	7	3
Office work	20	17	9	15
Health care	56	65	33	35
Other	8	8	3	4
Heavy physical work index (1–4)† [mean (SD)]	2.0 (0.5)	2.1 (0.5)	2.0 (0.5)	2.0 (0.5)
Job control (1–4)† [mean (SD)]	2.6 (0.4)	2.5 (0.4)	2.6 (0.3)	2.6 (0.4)
Job demands (1–4)† [mean (SD)]	2.5 (0.3)	2.6 (0.3)	2.6 (0.3)	2.5 (0.3)
Supervisor support (1–4)† [mean (SD)]	3.0 (0.3)	3.1 (0.5)	3.1 (0.4)	3.0 (0.4)
Radiating pain (yes/no)	15/81	22/77	11/44	14/43
Job satisfaction (1–4)‡ [mean (SD)]	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)
Expectation of patients on return to work (1–5)† [mean (SD)]	3.6 (1.2)	3.6 (1.1)	3.4 (1.2)	3.5 (1.1)
Sick leave prior to inclusion (partial/full)	20/76	35/65	17/36	12/44
Baseline values outcome measures				
Sick leave (days) of current episode of LBP prior to inclusion [median (IQR)]	26 (19–36)	24 (18–30)	26 (19–33)	24 (19–32)
Functional status (RDQ) [mean (SD)]	14.9 (4.2)	13.8 (4.6)	14.4 (4.5)	15.8 (3.2)
Pain severity [mean (SD)]	6.5 (1.7)	6.3 (1.7)	6.6 (1.4)	6.7 (1.5)

* $P < 0.05$.

†A higher score means a higher level of physically demanding work, job control, job demands, supervisor support, and expectation of return to work.

‡A higher score means a lower level of job satisfaction.

IQR indicates interquartile range (25th–75th percentile).

A total of 243 eligible workers of 55 OPs were recruited from October 2000 until October 2002. Forty-seven workers did not meet the inclusion criteria. Consequently, a total number of 196 workers were randomized for the workplace intervention: 96 workers were assigned to the workplace intervention and 100 workers to usual care. Eighty-four workers recovered before 8 weeks after the start of sick leave, leaving 112 workers to be randomized for graded activity: 55 workers were assigned to graded activity and 57 workers were assigned to usual care. Sick leave data were collected for all 196 (100%) included workers. For 24 workers (12%), no follow-up data regarding the secondary outcome measures could be collected.

Patient Characteristics

Table 2 shows the baseline values of the outcome measures and the prognostic factors for all groups. If the distribution of a variable was skewed, median value and the interquartile range (IQR, 25th and 75th percentiles) are presented. Except for gender and age, only small differences were found between the baseline characteristics of both groups.

Workplace Intervention

The workplace intervention had an average duration of 24 days (SD, 22 days) and started at 26 days (median; IRQ, 19–36 days) after the start of sick leave. Fifteen ergonomists were involved in delivering the workplace interventions. Ten of 96 (10%) workers did not receive intervention: 5 workers returned to work before an ap-

pointment for the workplace intervention was made. Five workers did not participate in the workplace intervention due to a work scheduling problem ($n = 3$), a medical reason ($n = 1$), or a work conflict ($n = 1$). None of the workers stopped during this intervention. No adverse events or side effects were reported. Additional treatments in this group of 96 workers applied by other care givers than the OP were: regular physiotherapy for 62 of 96 workers, manual therapy for 21 of 96 workers, Cesar therapy for 5 of 96 workers, chiropractor care for 7 of 96 workers, and a visit to a neurologist for 8 of 96 and to an orthopedic surgeon for 2 of 96 workers. There were no statistical differences between the (co)interventions received by the workers who received the workplace intervention or not.

Graded Activity

Graded activity had an average frequency of 14.1 sessions (SD, 6.8) starting at 69 days (median; IRQ, 56–84 days) after the start of sick leave. Forty-seven PTs were involved in 16 PT centers. Nineteen workers out of 55 (35%) were not compliant for the following reasons: interference with other practitioners ($n = 3$), miscommunication ($n = 2$), change of function/job ($n = 2$), contraindications ($n = 5$), not able to follow regimen ($n = 3$), drop out from the program ($n = 3$), and distance to training center ($n = 1$).

Additional treatments in this group of 55 workers applied by other care givers than the OP were: regular physiotherapy 40 of 55 workers, manual therapy 22 of

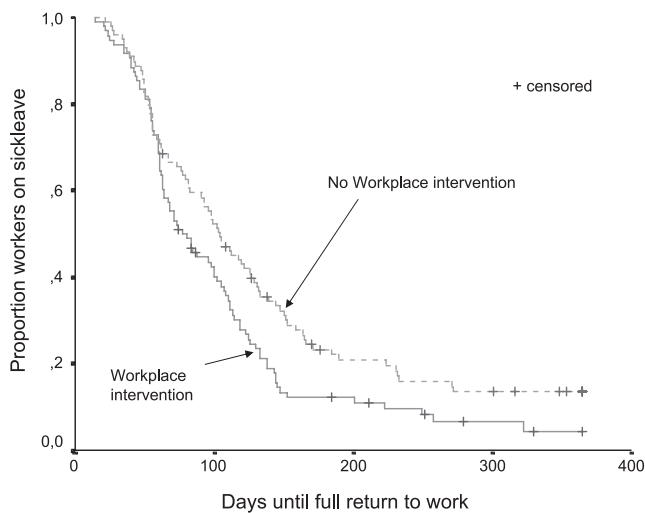


Figure 2. Survival curves of absence from regular or equal work for both the workplace intervention group and usual care group.

55 workers, Cesar therapy 5 of 55 worker, chiropractor care 5 of 55 workers, and a visit to a neurologist 6 of 55 and an orthopedic surgeon 4 of 55 workers. No adverse events or side effects were reported. There were no statistical differences between the (co)interventions received by the workers who received graded activity or not.

Sick Leave due to LBP

Intraclass correlation coefficients among OPs were estimated as <0.01 so all analyses were performed at the worker's level. The interaction between workplace intervention and graded activity was statistically not significant ($P = 0.61$). Therefore, one multivariate Cox regression model was used to describe the effectiveness of the workplace intervention and graded activity, separately, adjusting for the effect the other intervention and confounding factors. The effects of the combined intervention were calculated based on this model.

Workplace Intervention

In the univariate analysis, the time until full and lasting return-to-work in the workplace intervention group was 77 days (median; IRQ, 56–126 days) compared with 104 days (median; IRQ, 56–166 days) for the nonintervention group. This difference was significant (log-rank test; $P = 0.02$). The curves of both groups over 12 months of follow-up are shown in Figure 2. The total number of days of sick leave (including recurrences) during the 12 months of follow-up in the workplace intervention group was 84 (median; IQR, 58–132 days) compared with 105 (median; IQR, 60–166 days) for workers without a workplace intervention. By means of Cox regression analyses ($n = 196$), hazard ratios adjusted for graded activity, worker's functional status, and job control were calculated. The hazard ratio was 1.7 (95% confidence interval [CI], 1.2–2.3, $P = 0.003$), in favor of the workplace intervention group (Table 3). The number of workers who did not return to their own, full work for a long-lasting period during 12 months follow-up was 9 (9.4%) in the workplace intervention group *versus* 17 (17.2%) for workers who did not receive a workplace intervention.

Graded Activity

The time until full and lasting return to work in the graded activity group ($n = 55$) was 144 days (median; IQR, 113–233 days) *versus* 111 days (IQR, 74–153 days) for the workers ($n = 57$) without this intervention (log-rank test; $P = 0.030$). The total number of days of sick leave (including recurrences) during the 12 months of follow-up in the graded activity group was 145 (median; IQR, 119–233 days) compared with 111 (IQR, 74–164 days) for workers without graded activity. In multivariate analyses ($n = 196$), the adjusted hazard ratio was 0.4 (95% CI, 0.3–0.6, $P < 0.001$), in favor of the group without graded activity (Table 3).

Table 3. Results of the Univariate and Multivariate Survival Analyses Regarding Time to Full and Lasting Return to Work

	Univariate Analyses		Adjusted Hazard Ratios (95% confidence interval) for Return to Work (Cox regression analyses) ($n = 196$)*	
	No. of Days off Work (median)	Log Rank (P)	HR	P
Comparison 1				
Workplace intervention	77	0.02	1.7 (1.2–2.3)†	0.002
No workplace intervention	104			
Comparison 2				
Graded activity	144	0.03	0.4 (0.3–0.6)‡	<0.001
No graded activity	111			
Comparison 3				
Combined intervention	143	0.49	0.7 (0.3–1.2)§	>0.05
No combined intervention	126			

*There was no dependency of observations found between OPs. No interaction was found between workplace intervention and graded activity.

†Adjusted for effect of graded activity, worker's functional status, and job control.

‡Adjusted for effect of workplace intervention, worker's functional status and job control.

§Adjusted for independent effects of workplace intervention, graded activity, worker's functional status, and job control.

Table 4. Mean Improvements in Functional Status and Pain From Baseline at 12 Months and Differences in Effects Between the Groups (Intention-to-Treat Analysis)

Effects (N = 196)	Functional Status		Pain Intensity	
	Improvement at 12 Months [mean (SD)]	Effect (CI)*	Improvement at 12 Months [mean (SD)]	Effect (CI)*
Comparison 1: Workplace intervention				
Yes	9.0 (6.2)	-0.25 [-1.57 to 1.06]†	3.3 (2.6)	-0.20 [-0.75 to 0.35]†
No	8.1 (5.7)		2.9 (2.7)	
Comparison 2: Graded activity				
Yes	7.3 (6.2)	1.74 [0.07 to 3.42]‡	2.7 (2.6)	0.67 [-0.05 to 1.38]‡
No	9.9 (6.1)		3.7 (2.6)	
Comparison 3: Combined intervention				
Yes	8.3 (7.9)	1.49 [-0.33 to 3.31]§	2.9 (2.6)	0.47 [-0.42 to 1.35]§
No	8.7 (6.0)		3.3 (2.6)	

*The effect is the regression coefficient derived from longitudinal random coefficient analysis, which can be interpreted as the difference in adjusted improvement over time between the groups. No time interaction was found.

†Adjusted for the baseline value of the outcome measure, the effect of graded activity, gender, levels of OP, and time.

‡Adjusted for the baseline value of the outcome measure, the effect of workplace intervention, gender, levels of OP, and time.

§Adjusted for the baseline value of the outcome measure, gender, levels of OP, and time.

Combined Intervention

The time until full and lasting return to work in the combined intervention group ($n = 27$) was 143 days (median; IQR, 108–250 days) compared with 126 days (IQR, 83–171 days) for the workers ($n = 85$) without the combined intervention (log-rank test; $P = 0.49$). The total number of days of sick leave (including recurrences) during the 12 months of follow-up in the combined intervention group was 144 (median; IQR, 108–250 days) compared with 129 (IQR, 86–178 days) for workers without the group that not received the combined intervention. In multivariate analyses ($n = 196$), the adjusted hazard ratio was 0.7 (95% CI, 0.3–1.2, $P > 0.05$; Table 3).

Functional Status and Pain Intensity

Table 4 presents the mean improvements in functional status and pain intensity from baseline to 12 months. In addition, the differences in effects between the groups are presented as the regression coefficients derived from random coefficient analyses are shown.

Workers who received a workplace intervention, functional status, and pain intensity improved more during follow-up than workers without this intervention. However, this effect was not statistically significant. Conversely, functional status and pain intensity improved more during follow-up in the group that did not receive graded activity than the graded activity group. The difference in improvement was statistically significant for functional status. Finally, there were no significant differences in improvement of functional status and pain between workers receiving both workplace intervention and graded activity compared with workers who did not receive any of both interventions.

Discussion

A Canadian RCT⁷ was replicated in the Netherlands for workers sick-listed 2 to 6 weeks due to nonspecific LBP, to evaluate the effectiveness of workplace intervention as well as graded activity in a multidisciplinary biopsych-

social rehabilitation program. The main finding of this study is that the workplace intervention after 2 to 6 weeks of sick leave had a positive effect on return to work, whereas graded activity after 8 weeks of sick leave had a negative effect on return to work and functional status. The combined intervention had no effect. Workplace intervention reduced occupational disability due to chronic LBP at 12 months after the start of sick leave.

Comparison With Other Studies

Despite the different socioeconomic context, the results from the original Canadian study⁷ are, to a large extent, replicated in the Dutch study. Workplace intervention was effective on return to work for subacute LBP in both studies, whereas the exercise program was not effective in the Canadian study or even counterproductive in the Dutch study. In addition, other publications already showed that the implementation rate of the ergonomic solutions was similar in both studies.^{10,18} The findings regarding the effectiveness of workplace interventions confirm the results of a multinational cohort study: Workplace interventions are effective on return to work and effectiveness is not influenced by the socioeconomic system.¹⁹ It is likely that the working mechanism of workplace interventions is based on more or other mechanisms than simply reducing physical or mental workload. An additional explanation could be that the intervention changes as the result of a mediation process in the perceptions of both worker and supervisor about the worker's capabilities and the workplace system's opportunities for return to work. These findings are in line with the suggestion that failure for return-to-work in the (sub) acute phase of LBP is caused by a failed social transaction to achieve modified work rather than it is caused by the medical condition of a worker.^{17,20,21} As a consequence, medical treatments for LBP are not effective and may have the potential to delay return to work.^{22–24} In contrast to our findings, graded activity was effective in other studies.^{12,25} However, comparison is difficult because in

the mentioned studies graded activity was applied in the well-controlled setting of one company and the interventions included a workplace visit²⁵ or were administered at the workplace of the worker by in-company therapists.¹² So, the positive effect of graded activity in these studies might be due to the workplace component and/or the involvement of the stakeholders at the workplace.

Strengths and Limitations of This Study

A principal strength of this study is that, to our knowledge, this is to date one of the 2 RCTs⁷ that evaluated in one study the effectiveness of both workplace intervention and graded activity components of multidisciplinary rehabilitation for LBP. Another strength is that a cross-national comparison in different socioeconomic settings could be made due to comparable design and interventions.⁸ Finally, the generalizability of the results is good due to the pragmatic RCT design and setting in the general worker's population.

Obviously, there were also some limitations. First, blinding of the patients and healthcare providers was impossible due to the character of the workplace intervention and graded activity. However, by deriving sick leave data from automated databases, information bias for our primary outcome measure was avoided. Although a Hawthorne effect could not be ruled out, comparable usual care interventions were given to all patients. Second, randomization was conducted at the OP level, whereas analyses were conducted at the worker's level. However, in multilevel analyses, no dependency of observations was found between OPs. Finally, workplace intervention was applied earlier than graded activity. Therefore, it is not allowed to compare the effectiveness of both interventions. However, timing of graded activity was comparable with other studies^{12,25} and therefore cannot explain the negative effect.

Impact of This Study

This RCT adds important evidence to the current limited evidence on the effectiveness of workplace intervention and graded activity for multidisciplinary rehabilitation of LBP.^{5,6} Principal meaning of this study is that physicians should recommend workplace intervention for the multidisciplinary rehabilitation of LBP after 2 to 6 weeks of sick leave. Graded activity after 8 weeks of sick leave cannot be recommended based on this study. From a societal perspective, the impact of workplace intervention on the reduction of costs due to sick leave and disability pensions appears to be important. However, the cost-effectiveness of multidisciplinary rehabilitation, including workplace intervention, will be described in a separate paper.

Key Points

- Workplace intervention accelerates return to work for workers sick-listed 2 to 6 weeks due to LBP compared with usual care, with a median difference of 27 days sick leave duration.

- Graded activity intervention after 8 weeks of sick leave is not advised. Workplace intervention in combination with graded activity is also not advised.
- The results from the original Canadian study (Sherbrooke study) are partly replicated and might be valid in other societies/socioeconomic context.
- The results can be easily generalized since we recruited from a wide variety of professions and 81% (196 of 243) of all eligible workers could be included.

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