SPINE Volume 31, Number 10, pp 1075–1082
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The Effectiveness of High-Intensity *Versus* Low-Intensity Back Schools in an Occupational Setting

A Pragmatic Randomized Controlled Trial

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Study Design. Randomized controlled trial.

Objectives. To compare high- and low-intensity back schools with usual care in occupational health care.

Summary of Background Data. The content and intensity of back schools vary widely and the methodologic quality of randomized controlled trials is generally weak. Until now, no back school has proven to be superior for workers sick-listed because of subacute nonspecific low back pain.

Methods. Workers (n = 299) sick-listed for a period of 3 to 6 weeks because of nonspecific low back pain were recruited by the occupational physician and randomly assigned to a high-intensity back school, a low-intensity back school, or care as usual. Outcome measures were days until return to work, total days of sick-leave, pain, functional status, kinesiophobia, and perceived recovery and were assessed at baseline and at 3 and 6 months of follow-up. Principal analyses were performed according to the intention-to-treat principle.

Results. We randomly allocated 299 workers. Workers in the low-intensity back school returned to work faster compared with usual care and the high-intensity back school, with hazard ratios of 1.4 ($P = 0.06$) and 1.3 ($P = 0.09$), respectively. The comparison between high-intensity back school and usual care resulted in a hazard ratio of 1.0 ($P = 0.83$). The median number of sick-leave days was 68, 75, and 85 in the low-intensity back school, usual care, and high-intensity back school, respectively. Beneficial effects on functional status and kinesiophobia were found at 3 months in favor of the low-intensity back school. No substantial differences on pain and perceived recovery were found between groups.

Conclusions. The low-intensity back school was most effective in reducing work absence, functional disability, and kinesiophobia, and more workers in this group scored a higher perceived recovery during the 6-month follow-up.

Key words: low back pain, randomized controlled trial, occupational health care, back schools, sick-leave. **Spine 2006;31:1075–1082**

Work absenteeism and disablement are responsible for the largest amount of low back pain-related economic costs in Western societies.[1] The direct and indirect costs due to low back pain are estimated per year at U.S. $50 billion in the United States[2] and U.S. $5 billion in the Netherlands.[3] Most workers sick-listed due to low back pain recover quickly. However, workers with subacute low back pain, who have been off work for 1 to 2 months have an elevated risk of longer-term disability.[4] It is of high priority to develop interventions for this group of workers which speed up recovery and return to work (RTW).

In a systematic review, it was concluded that more intensive back schools in an occupational setting are more effective compared with the low intensity "Swedish Back School."[5] These more intensive back schools varied from 21 outpatient sessions to a 3- or 5-week inpatient program in a back clinic or rehabilitation center.[6–9] The randomized controlled trials (RCTs) reported in this systematic review showed a reduction in pain intensity or recurrences of low back pain but only included patients with chronic low back pain and did not assess the impact on sick-leave. One single, RCT, however, showed the effectiveness of the low-intensity Swedish back school in reducing work absenteeism in acute and subacute patients with low back pain.[10] Other studies included a mix of acute and subacute patients and found positive[11,12] and no effects[13] of low-intensity back schools on sick-leave. However, most studies examining the effectiveness of back schools are of low methodologic quality due to deficiencies in study design and performance.[5]

Clearly, there is a need for high-quality RCTs that assess the effectiveness of low-intensity back schools in an occupational setting in a group of workers sick-listed with subacute low back pain. Furthermore, RCTs that simultaneously compare back schools of different intensity in an occupational setting are missing.

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This study is granted by The Netherlands Organization for Health Research and Development (Zon/Mw), Dutch Ministries of Health, Welfare and Sports and of Social Affairs and Employment. The funding organizations had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

Acknowledgment date: July 1, 2004. First revision date: January 7, 2005. Second revision date: April 26, 2005. Acceptance date: June 23, 2005.

The manuscript submitted does not contain information about medical device(s)/drug(s).

Federal and Foundation 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.

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The aim of this RCT is to study the effectiveness of a low- and a high-intensity back school, compared with usual care, on RTW in workers who are sick-listed for a period of 3 to 6 weeks due to nonspecific low back pain.

■ Methods

Study Design. The study is designed as an RCT, approved by the Medical Ethics Committee of the VU University medical center, Amsterdam. A description of the design of this RCT can be found elsewhere.[14]

Study Population. Workers sick-listed for a period of 3 weeks due to low back pain who visited their occupational physician (OP) at one of eight participating occupational health services. At the OP visit, they were informed about the trial and, if willing to participate, workers signed informed consent. Inclusion criteria were: nonspecific low back pain; being sick-listed (completely or partially) between 3 and 6 weeks; age 18 to 65 years; and ability to complete written questionnaires in the Dutch language. Exclusion criteria were: sick-listed due to low back pain less than 1 month before the onset of the current episode of sick-leave; specific pathology; pregnancy; and juridical conflict at work.

The intended study sample size of 300 workers, with minimally 70 workers in each treatment group, is sufficient to detect a mean difference of 5 sick-leave days due to low back pain between the three groups with $\alpha = 0.05$, and a power $(1 - \beta)$ of 90%, assuming a standard deviation of 10 days.[15] This same sample size is also sufficient to detect a 20% difference in perceived recovery.

Randomization. By using sealed, opaque envelopes, coded according to a computerized random number generator, workers were randomly allocated to either the low-intensity back school, high-intensity back school, or usual care group. A researcher (H.C.W.dV.), who was not involved in the selection and allocation of workers, prepared these envelopes. The assignment of workers took place by the researcher and research assistant after workers had completed a baseline questionnaire to collect demographic and prognostic information.

Blinding. During follow-up, workers were asked repeatedly not to indicate any information regarding their allocation to the researcher and research assistant. An independent research assistant extracted the work absence data. Occupational and family physicians and physiotherapists were not blinded for the allocated intervention but were not involved in the outcome measurements.

Interventions

Usual Care. Workers allocated to this group received usual care provided by the OP according to the Dutch guidelines for the occupational health management of patients with low back pain.[16] During consultation, the OP discussed with the worker the prognosis of the low back pain and the intended date of RTW. The worker was advised to continue normal activities as much as possible. After 12 weeks of continued sick-leave, the OP was advised to refer the worker to more intensive interventions such as back schools or a multidisciplinary rehabilitation program.[16]

Back Schools

Pretreatment Examination. Workers allocated to the low- or high-intensity back school received an individual 2-hour standard history-taking and physical examination to identify problematic activities they had to carry out at the workplace. Workers allocated to the low-intensity and high-intensity back school also received usual care provided by the OP, as described in the previous section. Consequently, the intended date of RTW was also discussed in the back school groups.

Low-Intensity Back School. This back school was based on the Swedish model and consisted of four group sessions once a week for 4 consecutive weeks. Each session was divided into an educational (30 minutes) and a practical part (90 minutes) and guided by written information and a standardized exercise program.[17,18] Workers were told that functional activities, like working, could be continued despite back pain. During the educational sessions, the physiotherapist discussed the workplace situation. Not only the most problematic activities experienced by the worker because of the low back pain will be discussed, workers also received information on how to cope with these activities. The practical part comprised of a standardized exercise program consisting of strength training and home exercises. The strength training involved progressive resistance training as well as functional exercises. Workers were instructed to perform exercises at home twice a day, and again if they had any recurrences of back complaints.

High-Intensity Back School. This back school was conducted twice a week, for 8 weeks. It consisted of 16 sessions, each lasting 1 hour, supervised by a physiotherapist.[19] Principles of cognitive-behavioral therapy were applied throughout the back school program.[20] The physiotherapist promoted a time-contingent increase in the level of activity. The first two sessions consisted of individual exercises simulating the activities the worker experienced as the most problematic at the workplace. Work-simulating and strength training exercises during subsequent sessions were performed with gradually increasing resistance. The workers were also given home exercises during the time they were participating in the back school program.

Contrast Between the Interventions. Commonly, workers sick-listed due to low back pain in the Netherlands also visit their general practitioner (GP). The GP provides referral to physiotherapy, manual therapy, Mensendieck exercise therapy, or other therapies.[21] An optimal contrast between the back schools and usual care was obtained by discouraging general practitioners to refer the workers who were allocated to a back school to previously mentioned therapies. Deviations from the back schools' treatment protocols or adverse events were reported by the physiotherapists on standardized forms. Workers in all treatment groups were allowed to use over-the-counter and prescribed pain and nonsteroidal anti-inflammatory drugs (NSAIDs).

Outcome Measures

Primary Outcome Measures. Sick-leave data were collected continuously from the electronic medical records of the participating occupational health service, which is valid and reliable.[22]

RTW was defined as the duration of work absenteeism in calendar days from the first day of sick-leave until full return to own work or other work with equal earnings for at least 4 weeks

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without (partial or full) dropout. We calculated the total number of sick-leave days due to low back pain. We also calculated the number of recurrent episodes of sick-leave due to low back pain and the total number of sick-leave days due to these recurrences. Recurrent episodes, monitored during 6 months of follow-up, had to be separated by at least 4 weeks of complete RTW.

Secondary Outcome Measures. Pain intensity was scored on a Visual Analogue Scale.[23] Functional status was assessed by the Roland Disability Questionnaire (RDQ).[24,25] Perceived recovery was scored on a 6-point Likert scale, ranging from "completely recovered" to "much worse."[26]

Success rates were calculated after dichotomizing perceived recovery in "improved" (completely recovered or much improved) and "not improved" (slightly improved, no change, slightly worse, and much worse). Kinesiophobia was measured with the Tampa Scale of kinesiophobia (TSK).[27,28]

Questionnaires were administered at baseline and at 3 and 6 months. Follow-up data concerning additional healthcare visits and treatments were collected every 6 weeks by diaries.

Statistical Analyses. Descriptive statistics were used to calculate the three groups' baseline characteristics.

The Cox Proportional hazard model was used to analyze differences in RTW. Log-log survival curves showed that the proportional hazard assumption was not violated.[29] The cumulative percentages of workers returning to work were displayed by survival plots.[30]

The Kruskall-Wallis and χ^2 tests were used to assess group differences with regard to the total number of sick-leave days and recurrent episodes of low back pain related work absence (dichotomized as "recurrent episodes" or "not"). Linear and logistic regression analyses were performed to analyze differences between groups at 3 and 6 months. Each secondary outcome was fitted into the models as dependent and treatment allocation as independent dummy variable. We measured and adjusted for prognostic indicators which differed at baseline between the treatment groups (Table 1) and showed to influence prognosis.[31–34] Functional status, which was the only variable that significantly differed between treatment groups at baseline, was adjusted for in all models.

Intention-to-Treat Analyses. Applying the intention-to-treat (ITT) principle, we included all patients in the analysis according to the group determined at randomization, including withdrawals and patients with poor compliance.[35] Four workers missed 1 or more items in the RDQ and TSK at baseline and during follow-up. We substituted these missing items by using the corrected item mean imputation method.[36] Subsequently, for workers of whom baseline or follow-up data were missing completely, we applied multiple imputation with NORM version 2.03.[37]

Sensitivity Analyses. To detect bias because of missing data and protocol deviations, per protocol and complete case analyses were performed in addition to the ITT analyses. For the per protocol analyses, only workers compliant to the complete treatment protocol were included. Missing data of this group of workers were substituted as described above. For the complete case analyses (listwise deletion), workers were omitted from the regression models if data were missing on any of the variables or follow-up measurements were wrongly timed.

A P value of less than 0.05 was considered to be statistically significant. Regression analyses were performed with Stata, version 7[38]; other analyses were performed using SPSS version 11.0.[39]

Table 1. Prognostic Factors and Baseline Values of Study Outcomes

	UC (n = 103)	LI (n = 98)	HI (n = 98)
Gender (male/female)	85/18	76/22	75/23
Age (yr) (mean ± SD)	40.7 ± 9.6	40.6 ± 10.2	39.5 ± 9.5
Days off work [median (IQR)]	28.0 (13.0)	29.0 (13.0)	29.5 (11.0)
Partial/full absence from work (n/n)	17/86	13/85	17/81
History of back pain (%)	88.1	77.9	86.0
Pain radiation in 1 or both legs (%)	48.5	43.2	50.5
Duration of complaints (weeks) prior to randomization [median (IQR)]	35.0 (28.0)	35.0 (28.0)	35.0 (28.0)
Functional status (RDQ) (mean ± SD)	9.8 ± 5.0	7.9 ± 3.9	8.1 ± 3.9
Pain intensity (VAS) (mean ± SD)	6.5 ± 2.0	6.8 ± 1.7	6.5 ± 1.6
Treatment expectations [median (IQR)]			
Occupational physician	7.0 (3.0)	7.0 (3.0)	7.0 (3.0)
Low-intensity back school	8.0 (1.0)	8.0 (1.0)	8.0 (1.8)
High-intensity back school	8.0 (1.5)	8.0 (2.0)	8.0 (2.0)
Years working in current job [median (IQR)]	7.0 (14.0)	4.8 (10.3)	7.0 (16.5)
Job satisfaction (%)			
Good	42.6	38.7	39.6
Reasonable	43.6	46.2	46.2
Moderate	10.9	8.6	12.1
Not good	3.0	6.5	2.2
Job Content Questionnaire (mean ± SD)			
Job control	56.7 ± 9.6	56.2 ± 8.6	54.7 ± 10.0
Job demands	32.7 ± 5.0	34.5 ± 4.7	33.9 ± 4.5
Social support	23.3 ± 3.3	23.0 ± 3.6	23.0 ± 3.3
Kinesiophobia (mean ± SD)	39.5 ± 6.1	40.7 ± 6.5	40.1 ± 6.6
Daily exposed to:			
Vibration tools (%)	20.6	18.2	27.4
Lifting >25 kg per day (%)	34.4	36.6	44.0
Bending and twisting (%)	49.5	65.6	52.5
Whole body vibration (%)	36.4	37.2	32.2
Stooping (%)	61.4	65.6	60.0
Education (%)			
Low	58.2	60.0	63.6
Moderate	32.7	30.0	25.0
High	9.2	10.0	11.4
Baecke Questionnaire (mean ± SD)			
Work Index	3.4 ± 0.5	3.5 ± 0.5	3.4 ± 0.6
Sport Index	2.5 ± 0.4	2.6 ± 0.4	2.6 ± 0.4
Leisure Time Index	2.8 ± 0.6	2.8 ± 0.7	2.7 ± 0.6
Pain coping (mean ± SD)			
Active	6.8 ± 1.2	6.8 ± 1.3	6.8 ± 1.3
Passive	6.4 ± 1.3	6.8 ± 1.4	6.5 ± 1.5

LI = low-intensity back school; HI = high-intensity back school; UC = usual care (for some values scores were missing at baseline).

■ Results

Subjects

A total of 814 workers were checked for eligibility from October 2000 until November 2002 in occupational health services, serving different plants, varying from office workers to heavy labor like steel construction workers. Most of the patients (63%) were excluded for vari-

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ous reasons: did not meet eligibility criteria, back school training center too far from worker's home address, occupational physician preferred a specific intervention for a worker, work contract of worker was ended, and the company of the worker changed from one occupational health service to another. The residual 299 workers were randomized to usual care (103 workers), or either low-intensity (98 workers) or high-intensity back school (98 workers). Figure 1 presents the patients flow through the study. In total, 44 (15%) workers withdrew from the study. Sick-leave data were complete for all workers at baseline and during follow-up (100%). For the mailed questionnaires, response rates were 72% and 67% at 3 and 6 months, respectively. Baseline characteristics between treatment conditions are presented in Table 1.

Content of Allocated and Additional Treatments

Of the 103 workers in the usual care group, 88 (85%) returned the diaries containing information about the content of their treatments. In this group, workers reported an average of 14 healthcare visits or treatment sessions: 49 had received physiotherapy, 19 manual therapy separately or in combination with physiotherapy, 6 Mensendieck or Cesar therapy, 1 had visited a chiropractor and another an expert in podology. Three workers had received an intervention comparable to the high-intensity back school; 36 workers had used pain medication (analgesics only) and 19 NSAIDs.

Workers who were allocated to the low- and high-intensity back schools reported on average 3 and 13 treatment sessions, respectively. Of the 98 workers allocated to the low-intensity back school, 75 (77%) completed all treatment sessions, 15 (15%) discontinued treatment, and 8 (8%) had not received treatment at all (Figure 1). One patient, referred to the low-intensity back school, was admitted by the treating physiotherapist to the high-intensity back school. Another worker received treatment by a psychologist. Alongside the low-intensity back school, 31 workers used pain medication (analgesics only), 12 NSAIDs and 1 received antidepressive drugs.

In the high-intensity back school group, 70 (71%) workers completed all treatments, 18 (18%) discontinued treatment, and 10 (10%) workers did not receive a treatment at all. One worker received 2 treatments by a psychologist. In the high-intensity back school group, 30 workers used pain medication (analgesics only), 19 took NSAIDs, and 1 took antidepressive drugs during treatment sessions.

Two workers in both the low-intensity and high-intensity back school groups received 8 additional exercise

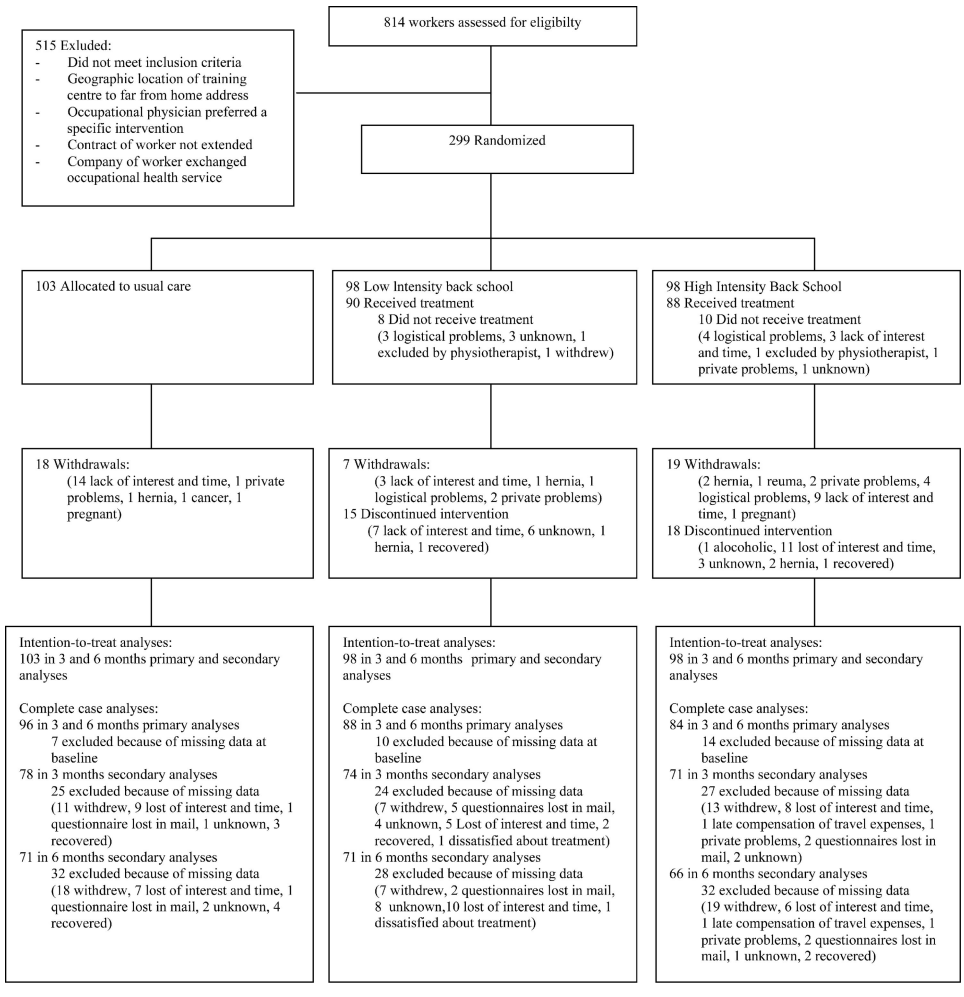

Figure 1. Flow of participants through the back school trial.

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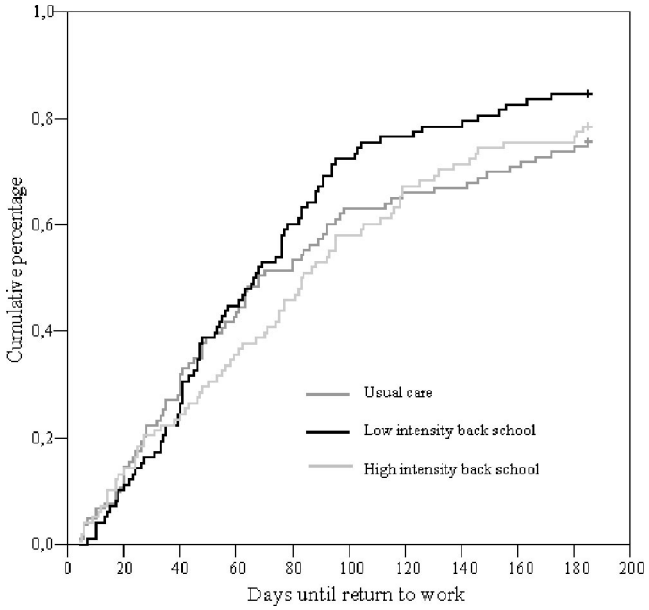

Figure 2. Cumulative percentages of RTW for usual care and the low intensity and high intensity back schools.

treatment sessions in the same training center. Of the workers who discontinued treatment, an average of 2 and 7 treatment sessions were completed in the low-intensity and high-intensity back school groups, respectively.

Primary Outcomes

Survival plots and RTW hazard ratios (HR) are presented in Figure 2 and Table 2, respectively.

The ITT analyses showed HRs of 1.4 (95% confidence interval [CI], 1.0–1.9; $P = 0.06$) and 1.0 (95% CI, 0.8–1.4; $P = 0.83$) for RTW with regard to the low- and high-intensity back school compared with usual care, respectively. The HR of 1.3 (95% CI, 1.0–1.8; $P = 0.09$) was in favor of the low-intensity compared with the high-intensity back school. Concerning the group of workers compliant to the treatment protocol, regression analyses resulted in a HR of 1.6 (95% CI, 1.1–2.3; $P = 0.01$) for the low-intensity compared with the high-intensity back school. All other analyses resulted in similar HRs for the complete case and per protocol analyses.

The median total number of days of sick-leave covering a period of 6-month follow-up was 68 for the low-intensity back school group and 75 and 85 for the usual care high-intensity back school groups, respectively. This difference was not statistically significant ($P = 0.28$). Also, the number of recurrences of episodes of back pain-related work absence, 7 for usual care, 5 for the low-, and 10 for the high-intensity back school, did not differ significantly between the three groups. The median total number of sick-leave days due to these recurrences was 7 in both the usual care and the low-intensity back school groups, and 13 in the high-intensity back school group.

Secondary Outcomes

Results on effectiveness of treatment for the secondary outcomes at 3 and 6 months are presented in Table 3.

In the ITT analysis, differences in functional status in favor of the low-intensity back school compared with usual care and the high-intensity back school were found at 3 and 6 months (Table 3). At 3 months, a difference of −2.2 (95% CI, −4.0 to −0.5; $P = 0.01$) was statistically significant for the low-intensity back school, compared with usual care. Workers treated by the high-intensity back school improved more on functional status at 3 months compared with usual care, but this improvement was not statistically significant. For kinesiophobia, beneficial effects were found at 3 months both in favor of the low- and high-intensity back schools compared with usual care. The difference of −3.5 (95% CI, −5.7 to −1.2; $P = 0.00$) at 3 months in favor of the low-intensity back school compared with usual care was statistically significant. The low-intensity back school also showed better results compared with the high-intensity back school at 3 and 6 months, although not reaching statistically significant differences. Mainly, small differences were found at 3 and 6 months for pain and perceived recovery among the three treatment groups. However, the low-intensity back school showed a trend for higher perceived recovery compared with usual care and the high-intensity back school at 6 months of follow-up. The same patterns in size and direction of treatment effects were found for the per protocol and complete case analyses (data not shown).

Adverse Events

Adverse events were reported by a total of 7 workers during or after treatment. Four workers, one in the usual care, one in the low-intensity back school group, and 2 in

Table 2. Hazard Ratios for the Difference in RTW for Usual Care Compared With the Low-Intensity and High-Intensity Back Schools

	Intention to Treat*			Per Protocol Analysis*			Complete Case Analyses†		
	n	HR (95% CI)‡	*P*	n	HR (95% CI)‡	*P*	n	HR (95% CI)‡	*P*
LI *vs.* UC	299	1.4 (1.0–1.9)	0.06	248	1.4 (1.0–1.9)	0.06	268	1.4 (1.0–2.0)	0.03
HI *vs.* UC	299	1.0 (0.8–1.4)	0.83	248	0.9 (0.6–1.2)	0.39	268	1.1 (0.8–1.5)	0.68
LI *vs.* HI	299	1.3 (1.0–1.8)	0.09	248	1.6 (1.1–2.3)	0.01	268	1.3 (1.0–1.9)	0.09

LI = low-intensity back school; HI = high-intensity back school; UC = usual care.
*Multiple imputation.
†Listwise deletion.
‡Adjusted for baseline differences of functional status (RDQ) and daily exposed to vibration tools.

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Table 3. Means, Standard Deviations, and Regression Coefficients (95% CI) for Differences in Secondary Outcomes Between Treatment Groups at 3 and 6 Months

		Intention-to-Treat Analyses*								
	N	UC [mean (SD)]	LI [mean (SD)]	HI [mean (SD)]	LI *vs.* UC Coefficient	*P*	HI *vs.* UC Coefficient	*P*	LI *vs.* HI Coefficient	*P*
3 months										
Functional status†	299	10.4 (0.7)‡	8.2 (0.6)‡	8.8 (0.6)‡	−2.2 (−4.0 → −0.5)‡	0.01	−1.6 (−3.5 → 0.4)‡	0.12	−0.7 (−2.6 → 1.2)‡	0.49
Pain†	299	4.6 (0.3)‖	4.0 (0.3)‖	4.3 (0.3)‖	−0.6 (−1.4 → 0.1)‖	0.11	−0.3 (−1.1 → 0.4)‖	0.42	−0.3 (−1.1 → 0.5)‖	0.43
Kinesiophobia†	299	39.5 (0.8)‖	36.0 (0.8)‖	37.6 (0.8)‖	−3.5 (−5.7 → −1.2)‖	0.00	−1.9 (−4.3 → 0.3)‖	0.09	−1.5 (−3.7 → 0.7)‖	0.19
		%	%	%	OR		OR		OR	
Perceived recovery	299	57‖	56‖	51‖	1.0† (0.5 → 2.0)[c]	0.90	0.8† (0.4 → 1.5)‖	0.44	1.2† (0.6 → 2.6)‖	0.60
6 months										
Functional status†	299	7.9 (0.6)§	6.9 (0.6)§	7.8 (0.6)§	−1.1 (−2.8→ 0.6)§	0.22	−0.1 (−1.9 → 1.7)§	0.88	−0.9 (−2.7 → 0.9)§	0.32
Pain†	299	4.0 (0.3)¶¶	3.5 (0.3)¶	3.9 (0.4)¶	−0.5 (−1.3 → 0.4)¶	0.27	−0.1 (−1.1 → 1.0)¶	0.89	−0.3 (−1.2 → 0.5)¶	0.42
Kinesiophobia†	299	36.8 (0.8)#	36.6 (0.8)#	37.9 (0.8)#	−0.2 (−2.5 → 2.0)#	0.84	1.1 (−1.3 → 3.6)#	0.36	−1.4 (−4.0 → 1.3)#	0.31
		%	%	%	OR		OR		OR	
Perceived recovery	299	54‡	64‡	50‡	1.5† (0.8 → 2.9)‡	0.18	0.8† (0.4 → 1.6)‡	0.57	1.8† (0.9 → 3.6)‡	0.07

LI = low-intensity back school; HI = high-intensity back school; UC = usual care; OR = odds ratio.
*Multiple imputation.
†Negative values indicate superior effects for the first treatment mentioned and are related to improvements for the workers.
‡Adjusted for RDQ at baseline and daily bending and twisting of the trunk.
§Adjusted for RDQ at baseline, daily working with vibrating tools, previous history of back pain, heavy lifting, and years of working in current job.
‖Adjusted for RDQ at baseline and working daily with vibrating tools, and daily bending and twisting of the trunk.
¶Adjusted for RDQ at baseline, previous history of back pain, and heavy lifting.
#Adjusted for RDQ at baseline, working daily with vibrating tools, daily bending and twisting of the trunk, previous history of back pain, and daily lifting.

the high-intensity back school group, were diagnosed by a medical specialist to have a herniated disc. Three workers, 1 in the low intensity and 2 in the high-intensity back school group, reported a strong increase in low back pain. However, this did not result in withdrawal from the study.

■ Discussion

This RCT shows positive effects on work absence for a low-intensity back school compared with the effects of a high-intensity back school and usual care during 6 months follow-up, in workers sick-listed for subacute nonspecific low back pain. Treatment effects on the secondary outcomes functional status, kinesiophobia, and perceived recovery were borderline significant at 3 and 6 months, also in favor of the low-intensity back school. Differences between groups concerning pain relief were small and not statistically significant.

Workers treated in the low-intensity back school group returned to work faster and were less days off work, compared with the usual care and high-intensity back school group. These finding are supported by the study of Indahl *et al* who also reported beneficial effects on work absence in sick-listed subacute patients with low back pain, who were referred to a low-intensity back school treatment.[11,12] Contrastingly, in a recent study,[40] a more intensive graded activity intervention, comparable with the high-intensity back school in our study, showed a beneficial effect on work absence. However, in this study, effects appeared slow, *i.e.*, at more than 50 days after randomization. The authors explained this delayed effect on RTW by the intensive nature of the graded activity intervention, which might create a lesser motivation of workers for RTW during active treatment periods. Moreover, consistent evidence exists that intensive intervention programs in an occupational setting, including back schools, are more effective for chronic patients with low back pain.[41,42] Our study results indicate that subacute sick-listed patients should be referred to lesser intensive back school programs to facilitate RTW.

Both back schools improved functional status of workers at 3 and 6 months compared with usual care, with the largest benefits found for the low-intensity back school. The difference in improvement of −2.2 on the RDQ at 3 months, in favor of the low-intensity back school, can be considered as a clinically important change.[43] Our study is the first RCT to show a statistically significant and clinically important short-term improvements on functional status, in favor of a low-intensity back school performed in an occupational setting.

Patients' beliefs about fear of reinjury are important factors contributing to long-term back disability or work loss.[44,45] These beliefs must be targeted preferably in the early phase of back pain development. Although effects diminished at 6 months, we found positive effects on fear of movement for the low-intensity back school compared with both other treatments at 3 months follow-up, *i.e.*, in the early stage of back pain. Other studies, which also investigated the effect of lesser intensive interventions in patients with low back pain in their subacute sick-leave period, presented comparable results.[46,47] These studies, including our low-intensity back school, embedded information on fear avoidance principles into their programs. In our opinion, this information, in cooperation with exercises, convinced workers to return to work at the end of the program.

Supported by cognitive-behavioral principles several studies showed that pain relief is not necessary to resume work.[48,49] Our study confirmed these findings, because comparison between treatment groups did not result in differences with regard to pain relief.

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Among the low-intensity back school in our study, recently RCTs investigated the effectiveness of other low-intensity interventions in workers on sick-leave due to subacute low back pain. These other low-intensity interventions were given to individual patients and did not include a supervised exercise program. Exercises were instructed to be performed at home or in the workplace. These interventions did not fully comply with the definition of a back school, *i.e.*, an educational program, including exercises, given to groups of patients and supervised by a paramedical therapist or medical specialist.[5] However, positive effects were found in favor of these other low-intensity intervention on sick-leave,[46,50–52] pain intensity,[51] disability and beliefs.[46] In conclusion, the results of these interventions confirm the promising effects of a low-intensity (back school) intervention found in our trial.

The strength of this RCT is that we were able to use blindly collected full sick-leave information for each worker in our analyses. A deficiency of this RCT was the low response over time concerning the secondary outcome measures. These low responses can be attributed to the use of postal questionnaires.[47] However, Figure 1 shows that nonresponse was equally distributed over each treatment group and that treatment related or trial related reasons did not dominate nonresponse. Furthermore, our sample size calculation showed that 70 workers were sufficient to detect true differences between the treatment groups with a power of 90% and a significance level of 0.05. We succeeded in enrolling this number of workers in each treatment group. Furthermore, the complete case analysis showed that nonresponse was not selective.

As recommended by Hollis and Campbell,[35] we performed a sensitivity analysis to explore if our assumptions about the missing data were valid to generalize our results to the study population at large. Missing data were substituted by applying multiple imputation, a new method to substitute data.[53,54] Subsequently, by using this technique, we compared the ITT with a per protocol and complete case analyses. These different procedures resulted in comparable treatment effects.

Our study proved that a low-intensity back school has beneficial short-term effects compared with care as usual and a high-intensity back school on sick-leave, functional status, and kinesiophobia. Workers were recruited by a large group of OPs attending a broad range of different workplace settings, which enhances generalizability of our findings. A limitation of our study is that we were not able to provide full information of the workers excluded from the study for various reasons related and not related to the inclusion criteria. However, we do not think that this has resulted in bias because most of these reasons may also occur during daily occupational health care. Bias would have occurred in all cases for which the OP required a specific intervention. However, such specific OP intervention happened before randomization; consequently, these workers were not part of our study sample.

Our study results showed that back school interventions to prevent subacute sick-listed patients to become chronic are better suited as low-intensity interventions. We further suggest that future interventions should contain a clear endpoint, including a preset date for full RTW accompanied by a key message to reduce fear of reinjury. Future research is needed to verify this recommendation and even more important to examine the cost savings of low-intensity back schools in contrast to high-intensity back schools in occupational health care. Lastly, our study results will refine current practice guidelines for occupational, as well as general physicians.

■ Key Points

- This is the first randomized controlled trial that directly compared a low-intensity and high-intensity back school with usual care in an occupational setting in patients on sick-leave because of subacute low back pain.
- A low-intensity back school is most effective in reducing work absence during 6 months of follow-up. A low-intensity back school is most effective in reducing functional disability and kinesiophobia during the 3-month follow-up.
- Low-intensity (back school) interventions may be promising for subacute patients.
- Future research is needed to examine the cost savings of adding low-intensity back schools to usual care compared with adding high-intensity back schools.

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