

The Effects of a Graded Activity Intervention for Low Back Pain in Occupational Health on Sick Leave, Functional Status and Pain: 12-Month Results of a Randomized Controlled Trial

Hynek Hlobil,^{1,3} J. Bart Staal,^{1,5} Jos Twisk,² Albere Köke,⁴ Geertje Ariëns,¹ Tjabe Smid,^{1,3} and Willem van Mechelen^{1,6}

Introduction: Behaviorally oriented graded activity interventions have been suggested for sick-listed workers with low back pain on return to work, but have not been extensively evaluated. **Methods:** One hundred and thirty-four workers were randomly assigned to either a graded activity intervention (n = 67) or usual care (n = 67) and followed-up for 12 months. **Results:** The graded activity group returned back to work faster with a median of 54 days compared to 67 days in the usual care group. The graded activity intervention was more effective after approximately 50 days post-randomization (HRR = 1.9, CI = 1.2–3.1, p = 0.01). Differences between the groups in number of recurrent episodes, total number of days of sick leave due to low back pain, and total number of days of sick leave due to all diagnoses, were in favor of the graded activity group, although not statistically significant. No effects of the graded activity intervention were found for functional status or pain. **Conclusion:** Graded activity intervention is a valuable strategy to enhance short-term return to work outcomes.

KEY WORDS: graded activity; low back pain; occupational health; return to work; sick leave.

INTRODUCTION

Nonspecific low back pain (LBP) is one of the most common complaints in the Western world, with a lifetime prevalence that can reach 85% (1). Although nonspecific LBP does not have a clear pathoanatomical substrate, and is considered a self-limiting benign condition

¹Department of Public and Occupational Health, VU University Medical Centre, Amsterdam, The Netherlands.

²Department of Clinical Epidemiology and Biostatistics, Institute for Research in Extramural Medicine, VU University Medical Centre, Amsterdam, The Netherlands.

³KLM Health Services, Schiphol, The Netherlands.

⁴Rehabilitation Center Hoensbroeck, Hoensbroeck, The Netherlands.

⁵Department of Epidemiology, Maastricht University, Maastricht, The Netherlands.

⁶Correspondence should be directed to Prof. Willem van Mechelen, MD, PhD, Department of Public and Occupational Health, Institute for Research in Extramural Medicine, VU University Medical Centre, 1081 BT Amsterdam, The Netherlands; e-mail: w.vanmechelen@vumc.nl.

in most patients, the disabling pain behavior can result in a disuse syndrome and chronic disability. From the occupational health care perspective, preventing long-term disability and sick leave is important. It seems appropriate to begin with an intervention in the sub-acute stage of LBP, i.e., between 4 weeks and 3 months of sick leave, taking into account the expected spontaneous recovery in the acute phase of LBP, and the necessity for early prevention of the development of chronic LBP (2–5). A promising intervention for sub-acute LBP is a graded activity intervention (GA), as first developed by Lindström *et al.* in Sweden. Yet, this type of intervention has rarely been evaluated outside of the referral clinic setting (6). In the present randomized controlled trial (RCT), effects of a GA intervention on return to work (RTW), functional status and pain severity were compared with usual care, in the context of a single company, within the special social-economic circumstances in the Netherlands. The short-term effects of this intervention after 3 and 6 months of follow-up have already been reported elsewhere (7) and this paper describes the effects over a 12-month follow-up period.

METHODS

Study Design and Population

The study was a single blind RCT, carried out in the occupational health services department of the Royal Dutch Airlines (KLM) at Schiphol Airport. The source population consisted of approximately 25,000 workers, employed by KLM. Workers who were sick-listed between the 1st of April 1999 and the 1st of January 2001 because of LBP were referred to the occupational physician (OP) for medical evaluation. The OP referred workers who were eligible for inclusion and willing to take part in the study, to the research assistant, who checked them against the inclusion and exclusion criteria. The inclusion criterion was nonspecific LBP for at least 4 weeks prior to inclusion in the study, with either full or partial sick leave due to LBP. Nonspecific LBP criteria excluded fractures, tumors, or infections; other exclusions were pain radiating below the knee, cardiovascular or medical contraindications for physical activity according to the Physical Activities Readiness Questionnaire (PAR-Q) (8), pregnancy, or legal conflict between worker and employer. Full or partial sick leave meant that the worker was listed as less than 100% fit for his work duties and was receiving full or partial sickness pay according to the Dutch Sickness Benefit Act.

Measurements were taken before randomization at baseline, and at 3, 6, and 12 months after randomization.

Treatment allocation was by means of block randomization into 10 strata, with blinding of the outcome assessors, as described in detail elsewhere (7). The Medical Ethical Committee of the VU University Medical Centre, Amsterdam, the Netherlands, approved the study.

Interventions

Workers who were randomized to either the GA group or the UC group received identical usual advice from the OP. This included medical examination discussions about managing sick leave, improving work conditions, and preventing recurrence of LBP. The OP in the Netherlands did not provide medical treatment, as this was provided by general practitioners (GP) or medical specialists.

Graded Activity Intervention

Before the start of the study, three physiotherapists were trained to deliver the GA intervention, consisting of 60 minutes exercise sessions given twice a week until the workers achieved full return to regular work, or when the maximum therapy duration of 3 months had been completed. At the start of the intervention, the physiotherapist inquired about the worker's medical history and carried out a brief physical examination. The intake was completed with an explanation about the benign nature and good prognosis of nonspecific LBP. The physiotherapist together with the worker determined a set of suitable physical exercises. During the first three sessions, the maximal performance was assessed for each exercise separately, and at the end of the third session, the worker was asked to propose a date for full return to regular work. This date would also serve as the end-point of the physical exercise program.

The worker and the physiotherapist agreed on a gradually increasing quota for each exercise and the date for RTW. This gradually increasing program according to a time-contingent principle started in the fourth session, at approximately 70% of the average performance level, as assessed during the first three sessions.

The GPs of the workers were informed about the study and the principles of the GA program. They were requested to adhere to the professional guidelines for LBP issued by the Dutch College of general practitioners, and not to refer these workers to other care-providers for any additional treatment for LBP during the course of the intervention.

Usual Care

There were no specific requirements or restrictions with regard to the type of treatment, except that the workers in the UC group were not allowed to receive any treatment in the physiotherapy practice at Schiphol Airport where the sessions for the GA group were held. The GPs were informed about the study and the allocation of their patient to the UC group, and they were asked to adhere to their professional guidelines for LBP (9).

Outcome Measures and Data-Collection

Outcome measures included total number of days of sick leave due to LBP, functional status and severity of pain. Follow-up measurements were performed at 3, 6 and 12 months after randomization. The sick leave data were collected from the electronic medical records of the occupational health services for the entire study period. Data about any treatment received during the study period other than GA were collected in both groups through diaries. The physiotherapists who applied the intervention reported data on the number of sessions completed in the GA program.

Sick Leave

For the purpose of this study, the first continuous period of sick leave due to LBP was defined as the number of days of sick leave from randomization until the date of full return to regular work. Workers, who returned to work partially, or with modified duties, remained on the sick list until they made a full return to regular work. Full return was operationalized as any full return to regular work with a minimum duration of 28 days. This means that

absences from work because of low back pain within 28 days of full return were considered as belonging to the same first continuous period of sick leave. This definition is based on then-valid Dutch Sickness Benefits Act, which considers recurrences of sick leave within 28 days as a continuous sick leave period. Completing 365 sick leave days entitled the worker to receive disability benefits. This operationalization of full return is an arbitrary one, as work absence due to LBP is determined not only by health-related factors but also by a large number of nonmedical factors.

The GA group and the UC group were compared with regard to the duration of the initial post-randomization period of sick leave due to LBP, the number of recurrent episodes of sick leave due to LBP, and the total number of days of sick leave due to these recurrent episodes. In addition, the total number of days of sick leave due to LBP and due to other diagnoses, and the total number of workers on sick leave at 12 months were calculated, and compared between the two groups.

Functional Status and Pain

Functional status was assessed by means of the Roland Disability Questionnaire (RDQ), which was scored by counting the number of positive responses. The individual scores can vary from 0 (*no disability*) to 24 (*severe disability*) (10,11).

Average pain intensity, experienced during the week preceding the assessment, was reported on an 11-point visual analogue scale (VAS) scale, ranging from 0 (*no pain*) to 10 (*very severe pain*) (12).

Statistical Analyses for Comparing the GA Group and the UC Group

The effect of the GA intervention on sick leave was analyzed by means of survival analysis. Kaplan–Meier curves were used to describe the distribution of duration of the initial post-randomization period of sick leave. A Cox multivariable regression model was used to estimate hazard ratios for RTW and 95% confidence intervals.

The incidence-rate of LBP recurrences, incidence-rate ratio and its 95% confidence interval were calculated in order to compare the differences between the groups. The total number of days of sick leave was analyzed by means of a Mann–Whitney *U*-test. The total number of workers in each group who were still on sick leave at 12 months was compared by means of a chi-square test.

The effects of the GA intervention on functional status and pain severity at the 12-month follow-up were analyzed by means of linear regression analysis. The group allocation was the dichotomous independent variable, where the baseline values of functional status and severity of pain were entered in the models as covariates.

In both the Cox regression analyses and the linear regression analyses, adjustments were made for age, gender, duration of sick leave due to LBP before randomization, and partial or full sick leave at baseline.

The statistical analyses were performed according to the intention-to-treat principle. An alternative per-protocol analysis, excluding all workers who were not treated according to the protocol, was only performed for the sick leave data.

The data were analyzed in SPSS statistical software (version 10.1, SPSS Inc., Chicago Ill). The level of statistical significance was set at $p < 0.05$.

RESULTS

Baseline Similarity and Dropouts

From the population of approximately 25,000 workers, 2550 cases of sick leave due to LBP for at least 1 day were registered during a 21-month period. Of these cases, 529 met the study criteria; of these, 150 workers were identified as eligible and referred by the occupational physicians to the research assistant for the intake procedure. A flow-chart of the participants in the trial and dropouts is presented in Fig. 1.

A total of 134 workers were included in the trial and randomly allocated to either the GA group ($n = 67$) or the UC group ($n = 67$). The data on base line characteristics of the GA group and the UC group did not show significant differences as reported in more detail elsewhere (7).

Loss to Follow-Up

A total of 14 workers withdrew from the trial, or did not show up for the follow-up measurements, despite several reminders. This group of 14 dropouts did not differ significantly with regard to baseline characteristics from the 120 workers who completed all follow-up measurements and questionnaires. Sick leave data were available for all 134 workers for the entire follow-up period.

Noncompliance

Of the 7 workers who withdrew from the graded activity intervention during the 12 months of follow-up, only three were not compliant with the protocol. One of them withdrew from the study immediately after randomization and refused to take part in the GA program and two others refused to carry on with the GA program after a few sessions, because they were disappointed with the content of the intervention.

Initial Post-Randomization Sick Leave Period

The median duration of the first continuous period of sick leave after the randomization was 54 days in the GA group and 67 days in the UC group. The first continuous period of sick leave was interrupted in only three GA and two UC cases for a mean duration of 6.6 days.

The Kaplan–Meier curves in Fig. 2 show the cumulative time to RTW to full duties during the 12-month follow-up period. The difference between the RTW of the groups over the entire follow-up year was just above the level of significance (log-rank test, $p = 0.06$). In the first 50 days after randomization, the RTW rate was almost the same in both groups. From approximately 50 days after randomization and onwards the RTW curves of the GA group and the UC group diverge with a more or less constant hazard ratio up to 299 days after randomization. At that point there was an acceleration in RTW rate in the UC group caused by RTW of seven workers in the UC group. In the GA group there were no more workers who returned to work after 277 days after randomization. At 12 months of follow-up, five

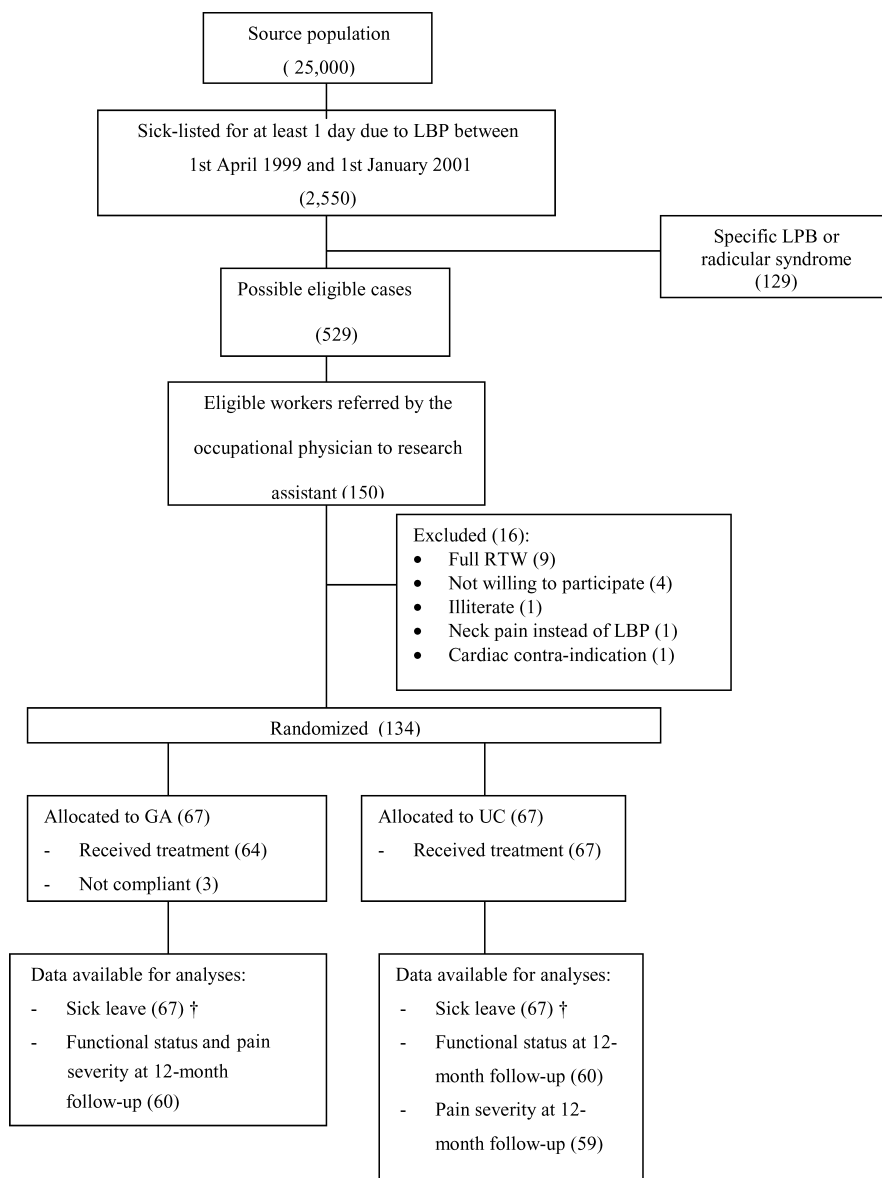


Fig. 1. Flow-chart of the participants and dropouts in the trial. *Between brackets: number of workers.

†Sick leave data were available for all included workers for the entire 12-month follow-up period.

workers in the GA group and eight workers in the UC group were still sick-listed and receiving partial or full disability benefits payments.

Hazard ratios for RTW were calculated for the period up to 50 days after randomization and between 50 and 365 days after randomization by means of Cox regression analysis for repeated events, similar to the method reported in a previous paper (7). For the period up to 50 days after randomization the calculated hazard ratio was 1.0 (95%

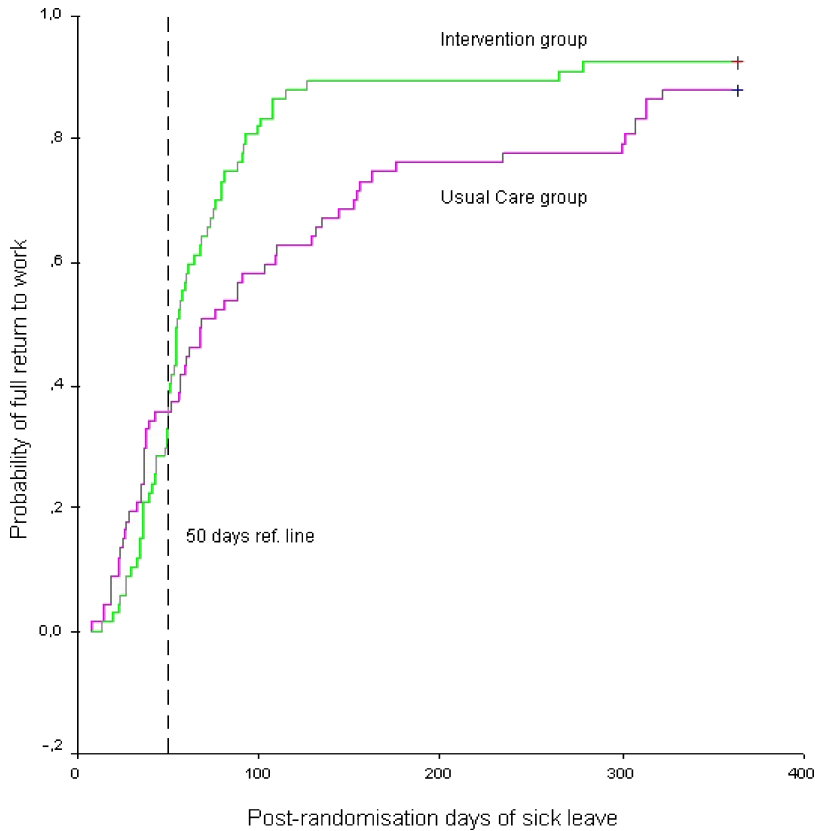


Fig. 2. Kaplan-Meier curves for the GA group ($n = 67$) and the UC group ($n = 67$).

$CI = 0.6-1.8$, $p = 0.99$). For the period from 50 days after randomization and onwards the hazard ratio was 1.9 (95% $CI = 1.2-3.1$, $p = 0.01$), in favor of the GA group. A per-protocol analysis, excluding the three noncompliant workers in the GA group who withdrew during the intervention period, showed an even higher hazard ratio for this period from 50 days onwards: 2.5 (95% $CI = 1.5-4.1$, $p < 0.01$), again in favor of the GA group.

Recurrences of Sick Leave Due to LBP

A total of 30 workers, 14 in the GA group and 16 in the UC group, had one or more recurrent episodes of sick leave due to LBP. The incidence-rate of these recurrences was 0.40 and 0.59 per person-year respectively in the GA group and UC group. The incidence-rate ratio, adjusted for time the subjects were on sick leave due to LBP or other diagnosis and thus not at risk for developing a LBP recurrence, was 0.68 ($CI = 0.04-1.32$). The recurrent episodes represented a total of 800 days in the GA group and 831 days in the UC group. The difference between the groups in the total number of days of sick leave due to these recurrent episodes of LBP over the entire 12-month follow-up period was not statistically significant ($p = 0.75$).

Table I. Total and Median Number of Days of Recurrent Episodes of Sick Leave Due to LBP, Other Diagnoses, centering and LBP and Other Diagnoses Together Over 12-Months of Follow-Up

	Graded activity (<i>n</i> = 67)		Usual care (<i>n</i> = 67)		<i>P</i> -value
	Days of sick leave	Median (IQR)	Days of sick leave	Median (IQR)	
LBP, including recurrences	6589	67 (49–67)	9,446	102 (37–233)	0.09
Other diagnoses	2376	15 (2–41)	2,016	6 (0–30)	0.11
LBP and other diagnoses together	8965	93 (70–169)	11,462	135 (79–299)	0.06

Note. IQR: interquartile range.

Total Number of Days of Sick Leave Due to LBP and Other Diagnoses

Table I presents the total number and the median of days of sick leave over the 12-month follow-up period due to LBP, due to diagnoses other than LBP, and due to all diagnoses together. The differences for all three comparisons between the GA group and the UC group were not statistically significant.

At 12-months follow-up after randomization, five workers in the GA group and eight workers in the UC group had not fully returned to regular work, a difference that was not statistically significant ($p = 0.38$).

Functional Status and Severity of Pain

Table II presents the results for functional status and pain severity. The mean score on the RDQ and the mean score for pain severity decreased almost equally for both groups from the baseline to the 12-month follow-up. There were no statistically significant differences in the improvement of these outcome measures between the groups.

DISCUSSION

This paper describes the effects of a GA intervention for nonspecific LBP, compared to UC during a 12-month follow-up period. The results confirmed a trend that was similar to that of the results at 3 and 6 months of follow-up: i.e., statistically significant effects with regard to RTW rate in favor of the GA group from approximately 50 days after

Table II. Mean Improvements in Functional Status and Pain From Baseline to 12-Month Follow-Up

Outcome measure	Graded activity	Usual care	Between-group difference ^a (95% CI)	<i>P</i> -value
	Mean (SD)	Mean (SD)		
Functional status (RDQ)	7.3 (6.0) (<i>n</i> = 60)	6.7 (6.7) (<i>n</i> = 60)	−0.6 (−2.8–1.5)	0.56
Pain severity	2.9 (3.1) (<i>n</i> = 60)	2.7 (3.0) (<i>n</i> = 59)	−0.2 (−1.2–0.8)	0.67

Note. CI: confidence interval; SD: standard deviation; RDQ: roland disability questionnaire.

^aAdjusted for age, gender, duration of sick leave due to LBP before randomization, and partial or full sick leave at baseline.

randomization onwards, and no differences between the groups in the improvement in functional status and pain severity. The fact that the improvement in functional status and pain severity did not differ between the groups, in contrast to the improvement of RTW rate in the GA group should be considered. Apparently, factors other than pain or functional status influence workers' decisions to return back to work. In this RCT, both groups received equal attention from the OP as the number of consultations was not significantly different ($p = 0.16$). There were also no other known factors that could account for a Hawthorne or placebo effect. We believe that shorter sick leave in the GA group is due to worker participation in scheduling their own RTW, using practical knowledge of rehabilitation possibilities at the workplace. The cognitive behavioral structuring of the physiotherapy and time-contingency of the GA intervention may also be important factors in faster RTW.

The reduction in the total number of days of sick leave due to LBP over a 12-month follow-up period was quite substantial in the GA group compared to the UC group, however this difference was not statistically significant. The nonsignificant findings may be explained by the fact that this trial was underpowered for the inherently skewed nature of length of sick-leave distributions. Nevertheless, these results give an indication of the magnitude of the possible reduction in work absenteeism that can be achieved.

In the UC group there were less days of sick leave due to other reasons than LBP: i.e., 2016 versus 2376 days. This statistically nonsignificant difference in favor of the UC group could be explained by the greater number of workers in the GA group who were at risk of becoming sick-listed due to other diagnoses than LBP.

The RTW curve for the UC group showed a considerable increase in RTW approximately 300 days after randomization. This increase in RTW rate occurred near the end of the 52-week period, coinciding with the end of the employer's obligation to continue full wage payments. According to the Dutch Sickness Benefits Act and Disablement Benefits Act, wage replacement can be reduced to 70% of the original wage after 52 weeks of continued sick leave. The RTW acceleration in the UC group is probably because these workers wanted to avoid the negative social and financial consequences of decreased benefits.

Comparison of the results of the present trial with those of other studies is hampered by the fact that RCTs on the effects of this specific intervention for LBP in a work setting are scarce. The Swedish study carried out by Lindström *et al.* (6) is the only RCT, as far as we know, that is comparable to this study with regard to treatment setting and content of the intervention. Lindström *et al.* found positive effects of the GA intervention on RTW after 2 years of follow-up in workers who were sick-listed due to LBP. Both the Swedish study and the present trial reported favorable results of a GA intervention on RTW, which may provide support that this type of RTW intervention is a valuable strategy to speed up the RTW of sick-listed workers with LBP. In other less comparable RTW interventions for sub-acute LBP, based on a mixture of exercise, education, behavioral treatment and ergonomic measures, interventions were also more effective than UC with respect to RTW (5,13–15).

In order to determine generalizability of findings within the KLM population regarding the first period of continuous sick-leave, the trial data were compared with data of workers from the source population who had been on sick-leave for nonspecific LBP during the period of inclusion for the intervention, but who had not been referred to the trial because of

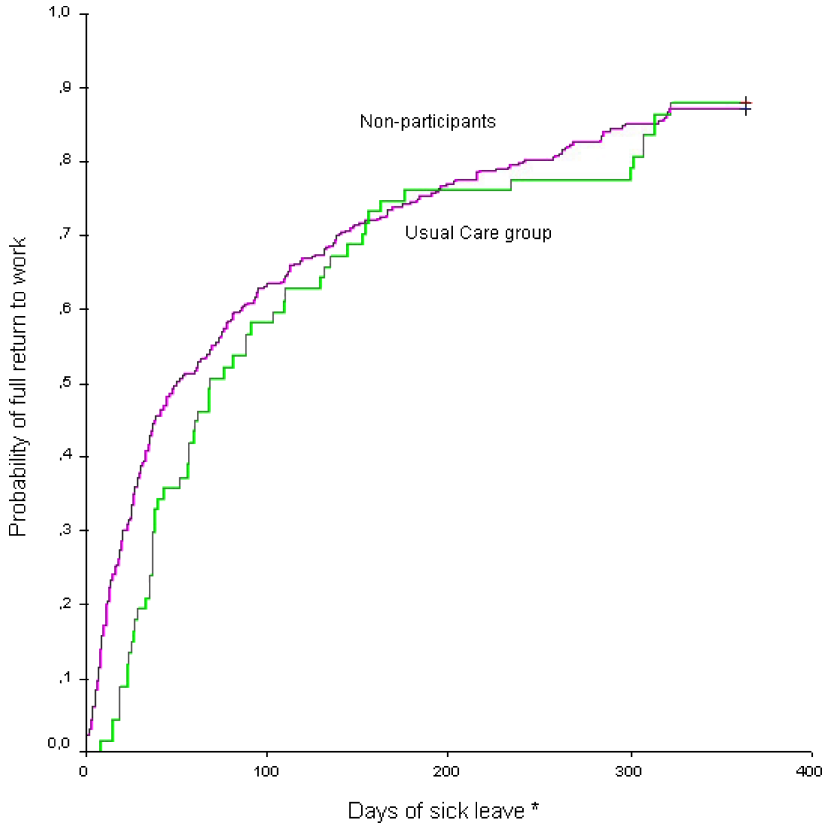


Fig. 3. Kaplan–Meier curves for the usual care group ($n = 67$) and nonparticipants ($n = 379$).
*Post-randomization days of sick leave for usual care group, and days of sick leave excluding the first 42 days of sick leave for nonparticipants.

various reasons (i.e., so-called “nonparticipants”). In total, it concerned 379 nonparticipants. These nonparticipants were comparable to the workers included in the trial regarding mean age (38 ± 8 versus 37 ± 8) and the number of days on sick leave prior to randomization (42 days). However, nonparticipants significantly differed ($p < 0.001$) from those included in the trial regarding sex distribution (i.e., 6% females in the trial population versus 26% in the nonparticipants). Sick-leave data from the first period of continuous sick leave of these nonparticipants were retrieved from the automated sick-leave registry in an identical way as the sick-leave data from the workers participating in the trial. Subsequently, sick-leave data from the first period of continuous sick leave of three groups (i.e., both trial groups and the nonparticipants) were compared by means of survival analysis. The Kaplan–Meier return-to-work curve for the nonparticipants (see Fig. 3) was almost identical to the return-to-work curve for the UC group (log-rank test: $p = 0.29$). This suggests that the selection of workers who were eligible and willing to participate in the trial was not different with regard to RTW behavior compared to the group of nonparticipants. Therefore, we believe that the results of the trial with regard to RTW may be generalizable to other KLM workers with nonspecific LBP. The fact that the trial groups counted a smaller proportion of females (6% versus 26%)

could be used as an argument against generalizability of the results to both sexes. However, sex-specific additional analysis of return-to-work data in the nonparticipants group showed statistically insignificant difference in this measure between the sexes (log-rank test; $p = 0.68$), which supports the generalizability of the results of the trial to both male and female workers.

As this trial and the study of Lindström *et al.* were both carried out within one single company, it remains uncertain whether the results can be generalized to occupational health care practice in various types and sizes of companies. In our opinion, there are some factors that are critical to the success of a GA intervention, such as the skills of the OPs and physiotherapists in treating patients, and effective communication between the OPs and the different caregivers, and between the OPs and the managers on the shop floor. Future researchers and policy-makers should consider these factors when studying, or when implementing this type of intervention in an occupational health care setting.

CONCLUSION

The GA intervention in comparison to UC resulted in a statistically significant speed up of initial RTW after 50 days of intervention for sick leave due to subacute LBP. The reduction in the number of days of sick leave due to LBP and due to other diagnoses was in favor of the GA intervention, but this reduction was statistically not significant. Factors that are critical for the success of the GA intervention should be taken into account when the intervention is implemented and these factors should be subject of future research.

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