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Lumbar Supports to Prevent Recurrent Low Back Pain among Home Care Workers

A Randomized Trial

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Background: People use lumbar supports to prevent low back pain. Secondary analyses from primary preventive studies suggest benefit among workers with previous low back pain, but definitive studies on the effectiveness of supports for the secondary prevention of low back pain are lacking.

Objective: To determine the effectiveness of lumbar supports in the secondary prevention of low back pain.

Design: Randomized, controlled trial.

Setting: Home care organization in the Netherlands.

Patients: 360 home care workers with self-reported history of low back pain.

Intervention: Short course on healthy working methods, with or without patient-directed use of 1 of 4 types of lumbar support.

Measurements: Primary outcomes were the number of days of low back pain and sick leave over 12 months. Secondary outcomes were the average severity of low back pain and function (Quebec Back Pain Disability scale) in the previous week.

Results: Over 12 months, participants in the lumbar support group reported an average of −52.7 days (CI, −59.6 to −45.1 days) fewer days with low back pain than participants who received only the short course. However, the total sick days in the lumbar support group did not decrease (−5 days [CI, −21.1 to 6.8 days]). Small but statistically significant differences in pain intensity and function favored lumbar support.

Limitations: Study participants were unblinded, and a substantial amount of missing data required imputation. Objective data on sick days due to low back pain were not available.

Conclusion: Adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism, among home care workers with previous low back pain. Further study of lumbar supports is warranted.

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Low back pain is a common problem that results in high medical expenses, work absenteeism, and disability (1). The reported 1-year prevalence ranges from 15% to 40% in a general population (2) and from 44% to 72% among home care workers (3, 4). Various ergonomic aids are marketed for the prevention of low back pain. Workers frequently use lumbar supports to prevent back pain (5), but the effectiveness of such supports remains unclear.

Recent systematic reviews of the sparse evidence on lumbar supports (6, 7) concluded that no evidence exists for the effectiveness of lumbar supports in the primary prevention of low back pain in the workplace, but 2 of the 4 included randomized, controlled trials (8, 9) reported that lumbar supports might be effective in workers with a history of low back pain (secondary prevention). However, these findings were derived from subgroup analyses, and evidence from direct research on secondary prevention was not available.

In cohort studies, a history of low back pain proved to be a strong predictor for the incidence of new episodes of low back pain (10–12). Home care workers with a history of low back pain may therefore be well suited to secondary preventive measures. In a previous uncontrolled feasibility study, we found that home care workers who had frequent episodes of low back pain reported adherence rates of 61% to 81% with lumbar supports and a 45% decrease in pain intensity when using lumbar supports (13). We designed the current trial to evaluate the effectiveness of adding worker-directed use of lumbar supports to a short course on healthy working methods to reduce low back pain and work absenteeism among home care workers with a history of low back pain.

Methods

Design

Our randomized, controlled trial included 2 groups. The control group received a short refresher course on healthy working methods provided by their employer at the start of their employment (**Appendix**, available at www.annals.org); primary and secondary care for the management of low back pain was available as usual (14). The intervention group received a lumbar support in addition

See also:

Print

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Appendix
Conversion of graphics into slides

Context

Lumbar supports are commonly used to prevent low back pain, but evidence on their effectiveness is lacking.

Contribution

This trial assigned 360 home care workers with a history of low back pain to a short course on healthy work habits, with or without worker-directed use of a lumbar support. Over 12 months, participants assigned to lumbar support had a similar number of sick days but fewer days with low back pain than did those assigned to the course only.

Implication

Adding lumbar supports to instruction on healthy work habits may decrease low back pain recurrence, but not absenteeism, among workers with previous low back pain.

—*The Editors*

to usual care. The intervention and data collection continued for 12 months after enrollment. The Medical Ethical Committee of the Erasmus University Medical Center, Rotterdam, the Netherlands, approved the study.

Participants

All participants were recruited from employees of a large home care organization in Rotterdam. During staff meetings, all present team members completed a brief survey about study inclusion criteria that was distributed and collected by the team managers. We included persons who performed medical care or domestic tasks as a home care worker, were experiencing low back pain symptoms at the time of inquiry or had experienced 2 or more episodes (on ≥2 consecutive days) of low back pain symptoms in the 12 months before the inquiry, did not have specific low back pain (for example, due to rheumatoid arthritis or vertebral fractures), and were not pregnant at the start of the study. Because of a possible association between lumbar supports and increased blood pressure and heart rate, we excluded workers receiving medical treatment for high blood pressure (15). Employees who met the inclusion criteria received detailed information about the trial, and those who agreed to participate provided written consent.

Randomization

In the Netherlands, home care workers provide 1 of 8 functions, each of which requires different skills and tasks. To ensure a balance in workload and working conditions between the 2 study groups, we stratified randomization by these 8 functions. We also stratified randomization by low back pain experience at baseline (current pain vs. past pain). The randomization process used a computer-generated random-number table with 16 strata (2 low back pain by 8 workplace functions), arranged in blocks of 8 within each stratum. After baseline measurements were completed, colleagues who were not otherwise involved in the study and who were blinded to participants' baseline characteristics used the random-number table to allocate each participant to 1 of the study groups.

Intervention

All participants in the intervention group were instructed to wear the lumbar supports on working days on which they had or expected they might develop low back pain. Participants could select 1 of 4 types of lumbar supports, supplied by Bauerfeind B.V., Haarlem, the Netherlands. LumboTrain and LumboTrain Lady are individually adjustable, hook-and-loop fastening, fully elastic supports that are available in 5 sizes for men or women. LumboLoc and LordoLoc are more structured supports, with integrated stays in the back, that have individually adjustable hook-and-loop fastenings and are available in 6 sizes. Participants chose the lumbar support on the basis of fit and wearing comfort, and they were not given advice to direct their choice from among the 4 available supports. When measured by the researcher for the lumbar support, the participants were advised to wear the support for a few days in a row, regardless of low back pain, in order to become accustomed to it. The expected duration of wearability of the lumbar supports was 1 year. The costs of the lumbar supports were €75 for LumboTrain and LumboTrain Lady, €56 for LumboLoc, and €50 for LordoLoc.

Outcome Measures

Our primary outcome measures were the number of days that participants reported low back pain per month and the number of calendar days of sick leave that participants took during the 12-month intervention. Secondary outcome measures were the average severity of low back pain in the previous week, rated on a scale of 0 to 10 (16), and functional status in the previous week, measured by using a Dutch translation of the Quebec Back Pain Disability Scale (on which 0 corresponds to no disablement and 100 corresponds to fully disabled) (17, 18).

Participants used a calendar to record the days per month on which they experienced low back pain. The intervention group was also asked to record on the calendar whether they had worn the lumbar support; thus, the calendars also served as a monitor for adherence to therapy. The calendars were collected for review after 1, 3, 6, 9, and 12 months. The number of calendar days of sick leave was derived from the staff register and was provided by the home care organization at the end of the study; this information covered 15 months, from 3 months before the start of the study until the end of the intervention. We could gather only general data on sick leave because employees are not obliged to specify their illness for the employer when they report themselves ill, and registration by a company doctor starts from 6 consecutive weeks of sick leave. We collected information on self-reported, low back pain–related sick leave; however, this was not a predetermined outcome, and the results should be interpreted cautiously.

We administered a questionnaire at baseline to obtain information on the secondary outcome measures and demographic characteristics; history of low back pain; job characteristics (among others, the Job Content Questionnaire, Dutch translation [19]); and other possible confounders, such as additional work (hours per week and type), preference for study group assignment, confidence in pain reduction with use of the lumbar support (scale of 0 to 10), and confidence in improved functioning (scale of 0 to 10). Follow-up questionnaires were administered at 3, 6, 9, and 12 months to measure the secondary outcomes. In the intervention group, these questionnaires also measured the general satisfaction with the lumbar support (scale of 0 to 10), several items on comfort of wearing (5-point Likert scale), and adherence to use of the lumbar support (7-point Likert scale). We recorded spontaneously reported side events and asked participants about side effects in the questionnaires.

Statistical Analysis

We estimated that with a power of 80%, a significance level of 0.05, and an SD of 20 days, we would need 140 participants in each study group to demonstrate a difference of 7 days of low back pain per year or sick leave per year between the 2 groups. To prevent inadequate power because of participant withdrawal or low adherence to therapy, we sought to enroll 400 home health care workers.

We used a longitudinal marginal model with generalized estimating equation estimates to analyze the data, according to intention-to-treat principles. For the primary outcomes (number of days of low back pain and number of days of sick leave), we used a negative-binomial count data model with a log-link and an exchangeable correlation structure. Covariates (history of low back pain, body mass index, additional work, and pregnancy during follow-up) were added to the model separately and were used in the final model if they statistically significantly contributed to the model ($P < 0.05$). The scale scores of the secondary outcomes were analyzed by using a normal distributed model and an exchangeable correlation structure.

To investigate model misspecification and the effect of missing data, we performed sensitivity analyses in which we used various structures for the working correlation to estimate the models and used multiple imputation techniques to analyze 5 imputed data sets for missing data (20). For all analyses, we used SAS, version 9.1.3 (SAS Institute, Cary, North Carolina).

Role of the Funding Source

ZonMw is the national health council appointed by the Ministry of Health and the Netherlands Organization for Scientific Research to promote quality and innovation in the field of health research and care. The ZonMW Thuiszorgtechnologie Fonds funded this study. Lumbar supports were supplied free of charge by Bauerfeind B.V. ZonMW and Bauerfeind B.V. played no role in the design, conduct, or analysis of this study or in the decision to submit the manuscript for publication.

RESULTS

Participants

Between May and October 2003, 96 team managers returned 1355 inquiry forms. On these forms, 811 home care workers (60%) reported an episode of low back pain in the previous week or at least 2 episodes of low back pain in the past year. Of the 708 eligible home care workers, 360 (51%) completed the baseline questionnaire; 183 were randomly allocated to the intervention group and 177 to the control group (**Figure 1**). All participants completed the 12-month intervention by the end of November 2004.

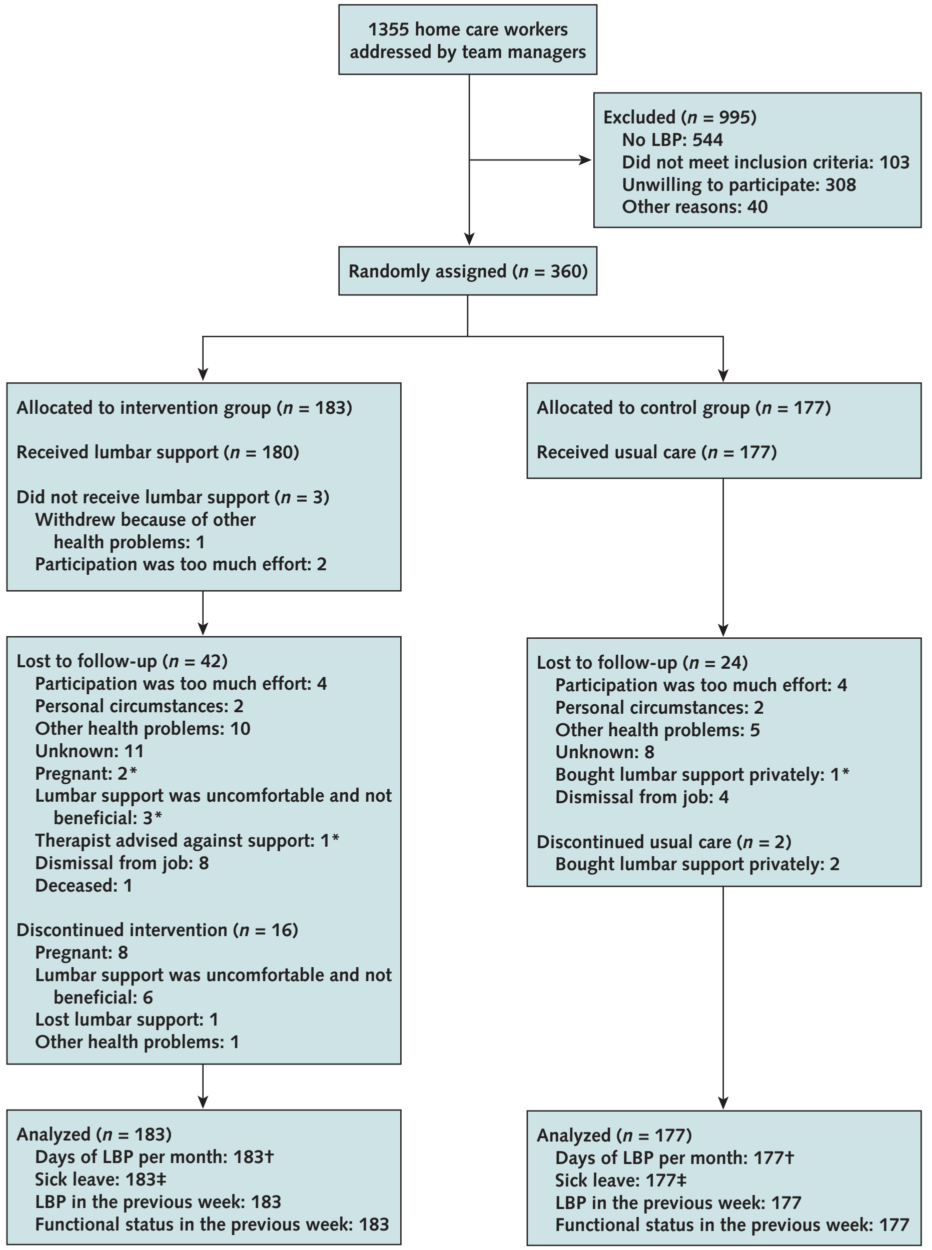
Table 1 shows baseline characteristics of the sample. Except for sick leave in the 3 months before the start of the intervention, the 2 study groups did not differ substantially at baseline. During the 12-month intervention, 66 participants (18%) withdrew from the self-reported measures, and data on sick leave registration were lost for 13 persons (4%) (12 were dismissed, and 1 died). **Figure 1** shows the distribution of the participants and reasons for withdrawal. In total, 327 persons (91%) returned calendars reporting the number of days of low back pain per month. On average, information was received for 8.7 calendar months (SD, 4.2; median, 11; range, 0 to 12). The mean registration period for sick leave after the randomization was 11.9 months (SD, 0.7; median, 12; range, 5 to 12). For the follow-up questionnaires, the average response rate was 80% (84% at 3 months, 79% at 6 months, 77% at 9 months, and 79% at 12 months). The baseline characteristics of persons lost to follow-up did not differ statistically significantly from those who completed the study.

Primary Outcomes

Days of Low Back Pain per Month

Overall, participants experienced low back pain for an average of 8.6 days per month (SD, 7.7; range, 0 to 30.3). The mean difference between the 2 groups was estimated in the generalized estimating equation model to be −53.7 days of low back pain per year (95% CI, −85.2 to −28.7 days per year; $P < 0.001$) in favor of the intervention group (**Figure 2**). In **Figure 2**, the low estimates in the first month are due to incomplete measures (mainly caused by delays in the in-company postal service and delays in measuring for the lumbar support). For the estimates per month, we back-calculated the difference from the log-linear parameters by using the sample's mean values for the covariate profile. The sum of the separate monthly estimates was used to calculate the yearly estimates. No statistically significant time effects were observed. Other statistically significant covariates in the final model were age, body mass index, functional status in the previous week, severity of low back pain in the previous week, maternity leave prevalence, and sick leave prevalence before the study period. The yearly estimate from the analyses on the multiple imputed data set was −52.7 days (CI, −59.6 to −45.1 days) (**Table 2**). In a post hoc, "worst-case" sensitivity

Figure 1. **Study flow diagram.**



LBP = low back pain. *Participants also cited "too much effort" and "unwilling to fill in questionnaires." †25% missing data. ‡1% missing data.

analysis, in which we replaced missing calendar data from the lumbar support group with 16 days of low back pain, the difference was still statistically significant in favor of the intervention group (−17 days per year [CI, −35 to −1.3 days per year]).

Absenteeism

The prevalence of general sick leave was 45 calendar days per year (SD, 67; range, 0 to 335). In the generalized estimating equation model, the groups did not differ for the estimated number of days of sick leave (−5.0 days [CI, −21.1 to 6.8 days]; $P = 0.45$) (**Table 2**). Significant covariates in the multivariate model were age, body mass index, maternity leave prevalence, sex, and sick leave prevalence before the study period. **Figure 2** shows the group estimates over time. The monthly and yearly estimates were calculated in the same manner as the estimates for days of low back pain.

Secondary Outcomes

Severity of experienced low back pain in the previous week and functional status in the previous week (Quebec

Back Pain Disability Scale) were the secondary outcomes of interest. We found small but statistically significant differences in favor of the intervention group for pain intensity (−0.6 points [CI, −1.0 to −0.1 points]; $P = 0.020$) and functional status (−4.1 points [CI, −7.5 to −0.8 points]; $P = 0.017$) (**Table 2**). The number of days of low back pain–related sick leave was estimated to differ by −4.8 days per year in favor of the lumbar support group (CI, −6.2 to −2.2 days per year; $P = 0.003$) (**Table 2**).

Lumbar Supports

At baseline, 4% of the sample was familiar with lumbar supports, and fewer than 1% of participants had recently used one but was no longer using it; 73% expected that a lumbar support would reduce pain, 76% expected that a lumbar support would increase functioning, and 77% would have preferred to participate in the intervention group. One person chose LumboTrain, 47 chose LumboTrain Lady, 30 chose LumboLoc, and 102 chose LordoLoc. Three intervention group participants left the study before the lumbar support was fitted. During the intervention, 3 control group participants purchased their own lumbar support. In the intervention group, 78% of participants wore the lumbar support for at least one third of the total number of days on which they reported low back pain. On average, participants wore the supports on 5.5 days per month (SD, 6.1; range, 0 to 27.3), which was 90% of the mean number of days with low back pain per month.

Nine persons (6%) said that the support was too uncomfortable to wear. Some practical disadvantages (for example, the support was "sweaty" on warm days), but no adverse events, were reported. In general, 74% of the sample was satisfied with the lumbar support, 66% reported that their low back pain was more bearable with the support, and 78% said that the support made them more aware of their working posture.

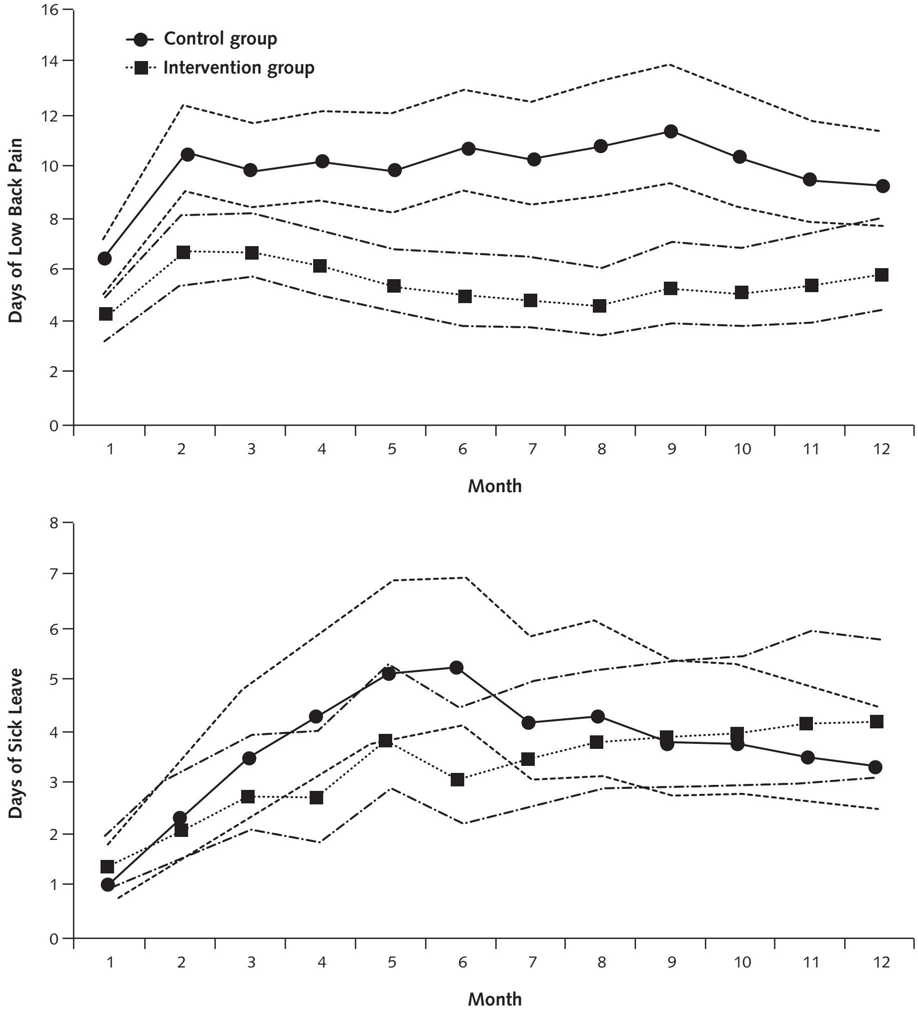
In post hoc analyses, we explored possible influences of adherence and the different types of supports on effectiveness. In the analyses of participants who adhered to use of lumbar support, we found stronger differences on all outcome measures, such as days of low back pain (−65 days [CI, −77 to −50 days] and sick leave (−13 days [CI, −25 to 3.3 days]. In contrast, participants who did not adhere to use of lumbar support did not differ from control par-

Table 1. **Baseline Characteristics of Participants in Intervention and Control Groups***

Characteristic	Lumbar Support Group (n = 183)	Control Group (n = 177)
Mean age (SD; range), *y*	41.8 (9.7; 19–62)	41.5 (9.8; 20–60)
Women, *n (%)*	180 (98)	172 (97)
Mean BMI (SD), *kg/m²*	26.6 (5.6)	27.1 (5.4)
Dutch/Caucasian ethnicity, *n (%)*	133 (73)	123 (70)
Mean time spent working (SD), *h/wk*	25.3 (7.9)	24.4 (8.4)
Employed with current home care organization <3 years, *n (%)*	52 (29)	53 (30)
Home care function, *n (%)*		
Domestic care A	60 (33)	59 (33)
Domestic care B	42 (23)	40 (23)
Nursing C	23 (13)	26 (15)
Nursing D	16 (9)	15 (8)
Medical nursing E	6 (3)	3 (2)
Medical nursing F	9 (5)	9 (5)
Ambulatory care	11 (6)	11 (6)
Maternity care	16 (9)	14 (8)
Mean additional time spent working (SD), *h/wk*	1.2 (4.1)	0.6 (2.7)
Have had LBP episodes for >1 year, *n (%)*	166 (91)	159 (90)
LBP in the past 12 months, *n (%)*		
1–2 episodes	28 (15)	32 (18)
3–5 episodes	43 (24)	33 (19)
>5 episodes	65 (35)	52 (29)
Continuous	47 (26)	52 (29)
Mean severity of LBP in the previous week (SD)†	4.7 (2.5)	4.7 (2.6)
Mean functional status in the previous week (SD)‡	29.6 (16.6)	30.7 (17.6)
LBP with radiation, *n (%)*	44 (24)	39 (22)
Consulted a physician for LBP in past 12 months, *n (%)*	114 (62)	110 (62)
Mean calendar days of sick leave in the 3 months before baseline (SD)	3.7 (13.5)	1.5 (6.1)
Mean calendar days of maternity leave during follow-up (SD)	6.9 (37)	1.4 (13)
Previous experience with lumbar support, *n (%)*	8 (4)	6 (3)
Preference for lumbar support group, *n (%)*	136 (74)	142 (79)
Expected increased functioning with lumbar support, *n (%)*	137 (75)	135 (76)
Expected reduction of pain with lumbar support, *n (%)*	130 (71)	132 (76)

* LBP = low back pain.
† Numeric rating scale on which 0 indicates no pain and 10 indicates worst pain.
‡ Quebec Back Pain Disability Scale on which 0 indicates no disability and 100 indicates completely disabled.

Figure 2. **Average number of days of low back pain (*top*) and general sick leave (*bottom*) per month.**



Estimates and 95% CIs were calculated from the model and are shown for the "mean covariate profile": a Dutch woman 41.7 years of age with a body mass index of 26.9 kg/m^2, a score for functional status in the previous week of 30.1, a score for severity of low back pain in the previous week of 4.7, a prevalence of sick leave before the study period of 2.6 days per month, and a prevalence of maternity leave during follow-up of 4.2 days.

ticipants for these variables. The various lumbar supports did not differ statistically significantly for any outcome.

DISCUSSION

This randomized, controlled trial demonstrates that the addition of lumbar supports to education about healthy work behaviors may prevent low back pain in home health care workers with previous low back pain. We observed almost 5 fewer days of low back pain per month among workers assigned to use a lumbar support, which is a clinically relevant reduction of 45% compared with the control group. All outcomes favored the lumbar support group, although not all reached statistical significance, and the effects were robust in sensitivity analyses.

Disappointingly, use of lumbar supports did not seem to significantly decrease total work absenteeism. Although workers assigned to lumbar supports had 53 days fewer with low back pain per year, the number of sick days was similar in both groups. However, our power calculations did not anticipate the observed average of 45 sick days per year (SD, 67), and this high prevalence did not differ from the general prevalence of sick leave in the home care organization in which this trial was performed. In an exploratory post hoc analysis, we found a difference in self-reported sick leave due to low back pain with lumbar supports. Further investigation of the relation between the low back pain–related secondary outcomes and sick leave resulted in Pearson correlation coefficients of 0.07 and 0.23 between sick days and low back pain severity and function, respectively; these values suggest that low back pain contributed only modestly to absenteeism in total in our study sample.

Table 2. **Adjusted Comparisons of Primary and Secondary Outcomes in Intervention and Control Groups***

Outcome Measure	Lumbar Support Group	Control Group	Difference (95% CI)	*P* Value
Primary				
Mean calendar days of LBP	71.7	124.4	−52.7 (−59.6 to −45.1)†	<0.001
Mean calendar days of sick leave	38.5	43.5	−5.0 (−21.1 to 6.8)‡	0.45
Secondary				
Mean severity of LBP in the previous week§	4.0	4.6	−0.6 (−1.0 to −0.1)	0.020
Mean functional status in the previous week‖	26.2	30.3	−4.1 (−7.5 to −0.8)	0.017
Mean calendar days of self-reported LBP-related sick leave	3.2	8.0	−4.8 (−6.2 to −2.2)	0.003

* LBP = low back pain.
† Adjusted for age, body mass index, functional status in the previous week, severity of low back pain in the previous week, maternity leave prevalence, and sick leave prevalence before the study period.
‡ Adjusted for age, body mass index, maternity leave prevalence, sex, and sick leave prevalence before the study period.
§ Numeric rating scale on which 0 indicates no pain and 10 indicates worst pain.
‖ Quebec Back Pain Disability Scale on which 0 indicates no disability and 100 indicates completely disabled.

In the intervention group, the secondary outcomes of severity of low back pain in the previous week and functional status in the previous week statistically significant improved (by 13% and 14%, respectively) compared with the control group. The clinical relevance of these observed effects is uncertain. Clinically relevant, within-participant decreases of 2 points for pain on an 11-point numeric rating scale and more than 10 points on the total functional status scale represent great improvement in patients with acute and chronic low back pain (21–23). However, low back pain fluctuates over time, with frequent recurrences or exacerbations (24), and we arbitrarily measured at 4 predefined points, regardless of whether participants had an exacerbation. We therefore consider our findings for secondary outcomes to support the findings for the primary outcomes.

The overall good adherence (78%) in our study underscores the observed feasibility of using a lumbar support as a secondary preventive measure in home care situations (13). The experienced benefit, therefore, most likely outweighs the discomfort of the device.

Similar to other studies of the effect of wearing a lumbar support, we could not include a placebo lumbar support group. Consequently, the control group was not blinded, which increases the chance of measurement bias, especially when self-reported measures are used. The magnitude of this possible bias is unclear, but given that participants had positive expectations of the lumbar supports, an overestimation of the effect would be the more obvious direction for bias (that is, persons who were not initially assigned to receive a lumbar support may have overreported their problems because they were disappointed to not be included in the intervention group).

The lack of blinding, missing calendar data, and limited ability to draw definitive conclusions about work absenteeism given the high prevalence of absenteeism in the study population are limitations of our study. In addition, we studied a predominantly female population of Dutch home care workers. The efficacy of lumbar supports should be investigated in different working populations and settings and with different co-interventions. Positive secondary preventive effects were reported for warehouse workers and freight personnel in subgroup analyses of 2 primary preventive trials (8, 9). Better insight into determinants of adherence is needed, as is greater knowledge of possible mechanisms of action, especially in working situations, so that lumbar supports can be offered to targeted groups (25). Nevertheless, low back pain remains a major problem in industrialized countries, and lumbar supports may be a valuable addition to secondary prevention strategies in the workplace.

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Appendix: Short Refresher Course on Healthy Working Methods

The yearly short refresher course on healthy working methods was not an intervention from our research group. Rather, it is part of the health and safety policy from the home care organization, as regulated by national legislation. All employees from the home care organization received this education, which was taught by the in-house health and safety executive. The course consisted of 2 hours of practical training and a theoretical component. During the practical training, participants learned the ergonomics of common tasks, such as cleaning the domestic environment or patients, transferring patients, or putting on elastic stockings, and practiced these tasks. The theoretical component consisted of a leaflet and playing board games that were developed to refresh and discuss knowledge on healthy working methods. The course was taught in group settings and was geared toward the specific functions. In the Dutch home care setting, this course is considered part of usual care; in other settings, however, this might not be the case.