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Respondents with mild LB symptoms were randomized into the Back Book (control) Back Book+Advice (intervention) groups. Both occupational health (OH) interventions were effective, but supplementary oral information was not more effective compared to the booklet alone. Policy implications: Patient advice is important in the OH setting, but we need more evidence of the effectiveness of various types of information.

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Face-to-face information combined with a booklet versus a booklet alone for treatment of mild low-back pain: a randomized controlled trial

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Objective The aim of this study was to determine the effectiveness of face-to-face information for the treatment of mild low-back pain (LBP) in an occupational health (OH) setting.

Methods We conducted a 48-month randomized controlled trial (RCT) with two 1:1 allocated parallel groups of forestry company employees. Eligibility criteria included permanent employment, age <57 years, and mild LBP [visual analogue scale (VAS) 10–34 mm] in a survey. The intervention group received the *Back Book*, an information booklet on how to manage LBP, with an additional face-to-face review of the booklet by an OH nurse. The control group received the booklet only. Primary outcomes were physical impairment (Roland-Morris 18-item (RM-18) Disability Questionnaire), LBP (VAS 100 mm), health-related quality of life [15-dimensional quality of life (15-D)] during two years and sickness absence (SA) up to four years. Participants were assigned using block randomization with a computer-generated scheme.

Results The RCT comprised 181 participants (72% male, mean age 44 years). There were no differences between the treatment arms in any of the primary outcomes at any time point. At 24 months, the mean group differences (intervention versus control) were: RM-18: 0 [95% confidence interval (95% CI) -1–1], VAS: 3 mm (95% CI -3–8), and 15-D 0.00 (95% CI -0.02–0.02). The difference in cumulative sickness absence days at 48 months were -3 (95% CI -28–21) for total and 1 (95% CI -3–5) for LBP specific sick leaves. Exploratory analysis revealed no differences at subgroup-levels either.

Conclusions Face-to-face patient information by an OH nurse in addition to a booklet was not more effective than the booklet alone in treating employees with mild LBP in an OH setting.

Key terms Back Book; employee health; intervention; intervention study; occupational health; patient information; secondary prevention; sickness absence.

Healthcare professionals deliver appropriate patient information in order to improve patients' understanding of the medical condition and prognosis. Patient information is also used to provide reassurance and help the patient to cope with the problem by enhancing self-management of the symptoms (1–4). Personal information is often reinforced with educational booklets. Such a combination seems to increase patients' motiva-

tion for self-care (5, 6). Educational booklets are used across specialties, eg, in prevention of oral cancer (5) and type-2 diabetes (7), hypertension (4) and low-back pain (LBP) (8).

Apart from the pieces of information, patient education includes the systemic experience of either psychosocial or behavior modification in personal contact with the patient (1, 9). A combination of booklet and

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individual advice is believed to have many advantages: patients may become more aware of treatment options and make the most of consultation. Usually, they also are able to recall the verbal advice better (3).

The *Back Book* is an educational booklet for non-specific LBP. It is based on the biopsychosocial model and focuses on attitudes and inappropriate behavior and includes information of how to cope with LBP and avoid re-exacerbation of LBP (2, 10). It also emphasizes that one should get back to normal activities, including returning to work, as soon as possible (3). As the booklet is easy to deliver, inexpensive, and innocuous (11), it has become widely used and is considered to be feasible also in the treatment and promotion of self-care among LBP patients (2, 12–14). Although the *Back Book* was introduced more than a decade ago and there is only limited evidence on its effectiveness (3), the content of the booklet is well in line with the general LBP guidelines (15–17).

According to the Finnish Occupational Health Care Act, employers are obliged to arrange occupational health (OH) service for their employees in order to prevent work-related health risks and protect and enhance safety, work ability, and general health of the workforce. OH services typically manage prevention of general illnesses and comprehensive primary care in addition to specific occupational hazards and diseases. Already for a decade, the coverage of OH services has been almost 90% of the total Finnish workforce (about 2.2 million in 2010) and almost 1 million health check-ups are performed in OH care annually (18). Well-defined, easy, applicable and cost-effective means for (secondary) prevention of LBP and subsequent work disability are desperately needed in OH services (15). For these reasons, educational booklets may be well-suited instruments to be used in OH services either alone or as an adjunct to personal, face-to-face information. Miscellaneous information about LBP is already widely provided in the clinical practice at OH, but the effectiveness of a uniform, low-back (LB) specific self-care information for low-level symptoms is not sufficiently known in the OH setting.

Most prior randomized controlled trials (RCT) concerning LBP in an OH setting have focused on employees already off-work (19–22). In their recent systematic review, Engers et al (9) concluded that at least 2.5 hours is required for the effectiveness of individual patient education concerning return to work. The studies in the review included patients who suffered from moderate-to-severe pain and physical impairment and were already off-work. Such a lengthy intervention would not be applicable in the OH setting for employees with only minor LBP and limitations. In addition, authors also state that "... research is also needed to evaluate what type of education is most effective or most efficient with respect to intensity and duration, and which healthcare professional can best provide patient education" (9).

We were primarily interested whether face-to-face information in addition to a patient information leaflet would be effective in improving the short- and long-term prognosis of mild LBP among employees in as pragmatic an OH setting as possible. We randomized employees with mild LB symptoms to receive the booklet alone or the booklet combined with booklet-based, face-to-face information, all delivered by an OH nurse. We compared the group differences using LB related outcomes and sickness absence (SA) during two- and four-year follow-ups, respectively.

Methods

Study design and ethics

The study design was a longitudinal cohort study with two embedded RCT.

All employees (2480) in a forestry company were invited to respond to a postal questionnaire on LBP and LB-related physical impairment. Based on the responses (rate 71%), employees were divided into three main categories: no or mild LB symptoms or moderate LB symptoms that potential hamper work. Two separate RCT were performed among the subjects with mild LB symptoms and moderate LB symptoms. There is no gold standard that would distinguish mild LBP from moderate symptoms. Although the cut-off limit was chosen arbitrarily in our study, the categorization follows some previous recommendations, eg, according to Hawker et al (23), mild pain can be categorized between 5–44 mm in the visual analogue scale (VAS) and moderate pain between 45–74 mm. This paper focuses on the RCT targeted at mild LB symptoms. The results of the other RCT have been published elsewhere (24). The South Karelian Central Hospital Research Ethics Board approved the study, which was performed according to the Declaration of Helsinki.

Participants

Employees younger than 57 years were eligible for the study if they reported LBP intensity between 10–34 mm on a 100-mm VAS during the past week and fulfilled at least one of the following criteria: (i) LBP duration of ≥ 2 weeks in the past 12 months, (ii) LBP that radiates below the knee level at the time of responding to the questionnaire, (iii) recurrent LBP (≥ 2 episodes during the past 12 months irrespective of their duration), and (iv) self-reported work absence because of LBP during the past 12 months.

Exclusion criteria were retirement within the time span of the follow-up, pregnancy, presence of acute nerve root compression symptoms, suspicion of malignancy.

nant tumors, recent fracture, severe osteoporosis or other specific disease preventing participation in the follow-up.

Included employees (N=312) were defined as a mild LBP cohort. Prior to the invitation to participate in the intervention study, a random sample of employees was extracted from the cohort in order to form a natural course (N=83) control group. The data of the natural course group is not shown in this paper.

The remaining employees (N=229) were invited to visit an OH nurse, who was specially trained in LBP and the main study procedures.

Randomization and blinding

An independent biostatistician prepared the stratification into two groups by using a computer-generated randomization table with a block size of 8. Based on the randomization scheme, a research assistant prepared the sealed envelopes before the start of the study containing either a referral to one of two groups: Back Book (BB) or Back Book with Advice (BB+A). The study design, implications of the trial, and alternative treatment options were explained to the study subjects personally at the randomization visit and also in the written informed consent form. After signing the informed consent form, the employee opened a sealed envelope containing their group assignment. The research assistant, OH nurse and the researchers were not able to identify the participants or the group assignments before the randomization. Due to the nature of the interventions, the participants and OH professionals were not blinded to the group assignment after randomization.

All employees would still get the best treatment and full attention of the OH service even if they did not want to participate. Information about the study was also provided in the company magazine and intranet. During the study period, the OH unit of the company operated as usual. Collaboration and communication between the study personnel, employers, trade union representatives, and the workers compensation board were assured prior to the study.

The study data were entered into the data file by persons who were independent of the research personnel in order to ensure blinded analysis.

After the randomization but well before the first 3-month follow-up visit, one person in the BB+A group retired and was excluded from the study. Thus, from a total of 182 randomized subjects, 181 were finally included in the study (table 1).

Interventions

At the beginning of the first visit, the OH nurse performed a clinical examination and explained the findings to the employee. If no exclusion criteria were noted and

the subject signed the informed consent, the OH nurse performed the randomization according to the scheme. The visit lasted about 60 minutes in the BB group. In the BB+A group, the face-to-face information required an additional 20 minutes.

Follow-up visits were scheduled with the OH nurse at 3, 6, 12, and 24 months after the baseline visit. At every study visit, the OH nurse checked the returned questionnaire information, performed a simple clinical examination, and answered any patient questions. Employees completed the baseline and follow-up questionnaires within one week prior to the visit date. The intervention groups were comparable concerning follow-up intervals, visit activity, or the time spent (30 minutes) at the follow-up visits.

All subjects had unlimited access to the usual OH care during the entire study period and were free to obtain additional healthcare services if needed.

The BB group (N=92). After the randomization, subjects received the *Back Book* information booklet from the OH nurse. The key messages of the booklet are in line with the national LBP management guidelines. The information is based on the biopsychosocial model and focuses on attitudes and inappropriate behavior concerning LBP. It also includes information on how to cope with LBP, avoid re-exacerbation of LBP, emphasizing that one should get back to normal activities, including work, as soon as possible. The *Back Book* was translated into Finnish from the original English version. The subjects in the BB group received no further intervention and acted as a control group.

The BB+A group (N=89). After the randomization, subjects received the *Back Book* from the OH nurse. In addition, the nurse also reviewed the booklet in detail, face-to-face with each worker by using a slide show prepared by the first author. Besides additional face-to-face information, there were no other contrasts between the intervention (BB+A) and control group (BB).

Outcome measures

The results of some previous studies in LBP show that there may be changes in, for instance, pain (25) or SA (26, 27), without any correlation between these variables. In this study, we have used several LB specific variables that were assessed separately in order to evaluate the effect of our intervention (25).

Primary. Physical impairment, intensity of LBP, health-related quality of life (HRQoL), and SA days were the primary outcomes in this study. The follow-up questionnaires included physical impairment [Roland-Morris 18-item (RM-18) Disability Questionnaire] (28–30),

Table 1. Baseline characteristics of study subjects. [BB+A=Back Book with advice intervention group; BB=Back Book control group; FABQ=Fear Avoidance Back Questionnaire; HRQoL=health-related quality of life; LBP=low-back pain; RM-18=Roland Morris Disability Questionnaire (18-items); SA=sickness absence; SD=standard deviation; VAS=visual analogue scale.]

Characteristics	BB+A (N=89)			BB (N=92)		
	%	Mean	SD	%	Mean	SD
Demographic features						
Age (years)	.	45	8	.	43	7
Body mass index (kg/m ²)	.	27	4	.	26	4
Male	79	.	.	66	.	.
Married	75	.	.	73	.	.
Smoker	30	.	.	28	.	.
High school diploma or vocational degree	79	.	.	75	.	.
General health						
Self-rated health status (moderate or better)	94	.	.	96	.	.
Low-back operation	6	.	.	4	.	.
Comorbidity other than LBP	35	.	.	33	.	.
Duration of LBP (years)	.	12	9	.	11	7
Work-related features						
Blue-collar	69	.	.	64	.	.
Shift work ^a	41	.	.	37	.	.
Work control (little or none)	19	.	.	25	.	.
Physical workload (1–5) ^b	.	3.3	1.0	.	3.4	0.9
Mental work load (1–5) ^b	.	2.8	0.8	.	2.8	0.8
Work ability (0–10) ^c	.	8.0	1.5	.	8.3	1.4
Total SA days during previous year ^d	.	12	18	.	9	12
Low-back-specific SA days during previous year ^d	.	1	3	.	2	6
Screening criteria						
Intensity of LBP (past week) (VAS: 0–100 mm)	.	20	7	.	20	7
LBP radiating below the knee	32	.	.	32	.	.
Subacute LBP (≥2 weeks in previous year)	38	.	.	33	.	.
Recurrent LBP (more than once/year)	92	.	.	96	.	.
Self-reported LBP work absence in previous year	23	.	.	21	.	.
Outcome variables at randomization						
Intensity of LBP (past week) (VAS: 0–100 mm)	.	18	17	.	21	19
Physical impairment (RM-18: 0–18)	.	3	4	.	3	3
Pain-related fear (FABQ: 13–78)	.	27	10	.	28	10
HRQoL score (15D: 0–1) ^e	.	0.918	0.060	.	0.922	0.065

^a Two- or three-shift work.

^b Range 1–5 indicates self-rated load level: 1=very heavy, 2=moderate, 3=intermediate, 4=rather light, 5=very light.

^c Range 0–10, where 0 is the lowest possible work ability and 10 is the best possible work ability.

^d Register data.

^e Based on 15-dimensional HRQoL score.

LBP during the past week (VAS) (31), and the HRQoL-measurement [15-dimensional quality of life (15-D)] (32).

SA data was obtained from the electronic medical records of the OH services at 12, 24, 36, and 48 months from the individual randomization date. Records were carefully checked for inconsistencies. Maternity or paternity leave and absence from work for care of a sick child were not included. Sickness absence data (days and periods) were analyzed in two ways: (i) LB-specific SA with no time-limit; (ii) any (=total) SA. However, SA episodes that were other than LB-specific and continued >30 days were omitted from the total number of SA in order to prevent severe diseases and sequels of injuries confounding the analysis. We were primarily interested in the shorter sick leaves because of the preventive approach in this study. The cut-off limit of 30 days per SA period was chosen arbitrarily.

Secondary. Pain-related fear [Fear-Avoidance Beliefs Questionnaire (FABQ)] (33) and SA periods were the secondary outcomes of the study. From the original SA data, SA periods were also calculated separately for the LB-specific and total SA at specific time points (12, 24, 36, and 48 months).

Additional analysis. We performed an exploratory subgroup analysis to find out possible effect modifiers concerning the SA results. The following a-priori-selected items were tested: follow-up year, group assignment, pain-related fear (FABQ), radicular pain, registered total and LB-specific (separately) SA days during previous year, self-informed SA (previous year), self-assessed work ability, physical and mental workload, shift work (two- or three-shift), self-assessed work control and work satisfaction, part-time or full employment, gender, and age at baseline.

Power calculations

In our population, the standard deviation of RM-18 score was estimated to be 4 units. A difference of 2 units between treatment arms will be detectable with 85% power in two-tailed tests with the alpha of 0.05 for a sample of 73 employees in each group; the standardized effect size will be 0.50.

Statistical analysis

All statistical analyses were performed at employee level, according to the intention-to-treat principle. Missing values in the questionnaire data were imputed using the last observation carried forward (LOCF) principle. Baseline characteristics were compared using descriptive statistics. The effectiveness of the intervention was estimated primarily by the difference of questionnaire

variables between two study groups (BB+A versus BB) at 3, 6, 12 and 24 month time points. Respective baseline values were used as covariates. The 95% confidence intervals (95% CI) for the mean differences between groups were computed using the generalized linear model (GLM). We used the statistical package of SPSS, version 17 (SPSS Inc, Chicago, IL, USA).

Regarding SA variables, the data were gathered at 12, 24, 36, and 48 months from the individual baseline date of each study subject. For all the SA variables, there was a great over-dispersion and excess of zeros in relation to the Poisson model. We used a hurdle model that consisted of a logistic part modeling the excess of zeros and a zero truncated negative binomial part modeling the count data.

In order to model nonlinear covariate effects and interactions between covariates, we used a hierarchical Gaussian process model with a neural network covariance function (34). The constructed hierarchical model included a common effect, an effect for the baseline, effects for each intervention group, and effects for each person (also called “random effects”). For the logistic model, we reported the probability of SA (days and periods) and odds ratios (OR) for the group differences, respectively. For the zero-truncated negative binomial model, we reported mean SA days or periods and mean ratios of the group difference. For all the reported values, we included 95% CI. The method is described in more detail elsewhere (24).

Results

Employee flow

Figure 1 presents the study flow chart. From company personnel of 2480, 1754 individuals (71%) answered the questionnaire. Based on the inclusion and exclusion criteria, 312 employees were eligible for the study. From this cohort, 83 employees were randomly selected into the natural course group (data not shown), 47 refused participation, and one was excluded. Finally, 181 persons were randomized into two intervention groups (BB=92, BB+A=89).

Loss to follow-up

Four subjects from the BB+A and five from the BB group quit the study due to personal reasons within the first three months but gave permission to use their data. Some participants from both groups failed to return the questionnaires at all time-points because of changes at work or reasons unknown to the researchers resulting in missing data. For the missing data, the LOCF principle was followed. At the final check-up visit, the activity

Figure 1. Flow diagram about the course of the study showing the number of subjects at different phases of the trial.

rates in the BB+A and BB groups were 75% and 73%, respectively.

Comprehensive SA data were available for all study subjects who were enlisted at the company for the entire follow-up period. Subjects who were no longer employed at the end of the follow-up years were excluded annually from the SA data analysis.

Primary outcomes

Physical impairment, low back pain (VAS) and HRQoL. Compared to baseline (table 1), there were no differences between study groups concerning physical impairment, intensity of LBP, or HRQoL at any time point during the 24-month follow-up (table 2). However, there were some differences during the follow-up time within the groups. Compared to baseline, physical impairment was lower in both groups up to 12 months but the trend remained only in the BB+A group until 24 months. Compared to baseline, VAS was lower up to 6-months but only in the BB+A group. Compared to baseline, HRQL was higher in the BB group up to 12 months (table 2).

Sickness absence days. In comparison with BB, BB+A did not reduce the probability or amount of total or LB-

Table 2. Results of primary and secondary outcomes (questionnaire variables) within the groups BB+A (Back Book with advice, N=89) and BB (Back Book, N=92) along with the group comparisons (BB+A versus BB) at the 2-year follow-up. [FABQ=Fear-Avoidance Beliefs Questionnaire (range 13–78); RM-18=Roland Morris Disability Questionnaire (0–18); SD=standard deviation; VAS=visual analogue scale, (0–100 mm); 15D=15-dimensional health-related quality of life (range 0–1, higher values indicate better quality of life), 95% CI=95% confidence interval]

Follow-up time	BB+A		BB		BB+A versus BB		
	Mean	SD	Mean	SD	MD	95% CI	P-value
Primary outcome							
Physical impairment (RM-18)							
3 months	3	3	2	3	0	-1–1	0.54
6 months	2	3	2	3	0	-1–1	0.97
12 months	2	3	2	3	0	-1–1	0.54
24 months	2	4	2	3	0	-1–1	0.74
Low-back pain (VAS)							
3 months	16	16	20	21	-3	-8–2	0.21
6 months	14	16	17	17	-2	-7–2	0.32
12 months	19	20	17	19	3	-2–8	0.30
24 months	20	23	18	20	3	-3–8	0.37
Health-related quality of life (15-D)							
3 months	0.92	0.07	0.93	0.06	-0.01	-0.02–0.00	0.07
6 months	0.92	0.09	0.93	0.07	0.00	-0.02–0.01	0.63
12 months	0.92	0.09	0.93	0.06	-0.01	-0.02–0.01	0.34
24 months	0.91	0.10	0.92	0.07	0.00	-0.02–0.02	0.99
Secondary outcome							
Pain-related fear (FABQ)							
3 months	28	11	26	10	2	0–4	0.06
6 months	25	10	25	10	0	-2–2	0.83
12 months	27	11	25	9	2	0–4	0.08
24 months	26	12	25	9	1	-1–4	0.22

specific SA days (table 3) at any follow-up point during four years. At the end of the 4-year follow-up, the mean differences of accumulated SA days between BB+A and BB were -3 [95% CI -28–21] (total) and 1 [95% CI -3–5] (LBP specific).

Between BB+A and BB, there was a difference of -124 (total) and 115 (LB-specific) days in the accumulated SA days in four years. The difference in total SA days favored the BB+A group and the difference in the LB-specific days favored the BB group. However, there were some differences during the follow up-time within the groups. During the first three years, the amount of LB-specific SA days per year decreased or remained at the same level, but increased during the fourth year in both groups (table 3). The increase of LB-specific SA days per year was significant between the 3rd and 4th year in both groups (BB+A: $P=0.001$; BB: $P=0.001$). A similar increase occurred also in the BB group concerning the amount of total SA days per year between the 2nd and 4th year ($P=0.030$). Thus, SA days seem to remain at the same level or even decrease during the first three years, but increased thereafter, in the fourth year.

Secondary outcomes

There was no consistent or clinically important difference in pain-related fear (FABQ) between the BB+A and

BB groups during the first two years (table 2). Concerning the differences within the groups during the follow up time, FABQ decreased in both groups up to 6 months but remained low until 24 months only in the BB group.

Sickness absence (SA) periods. In comparison to BB, BB+A did not reduce the probability or amount of total or LB-specific SA periods during the four-year follow-up (table 4). The mean differences of accumulated SA periods during four years between BB+A and BB were -1 [95% CI -5–2] (total) and -0.1 [95% CI -0.6–0.4] (LBP specific).

At the end of the 4-year follow-up, the difference in the sums of accumulated total and LB-specific SA periods between BB+A and BB were -184 and -20 periods, respectively. The group differences in both SA (total and LB-specific) periods favored the BB+A group.

Exploratory subgroup analyses. We performed an exploratory subgroup analysis from the total SA data. All-cause SA (one year prior to baseline) and shift work predicted the probability of total SA during the follow-up. However, the group difference was not significant for shift work.

Table 3. Sickness absence (SA) days [total and low-back (LB)-specific] in the BB+A (Back Book with advice, N=89) intervention and BB (Back Book, N=92) control groups and the change in time within the groups. Columns show the probability (P) for the occurrence of SA days (>0), odds ratio (OR) of the group comparison BB+A versus BB, the number of SA days in the intervention groups and the Ratio of the group comparison between BB+A versus BB. [95%CI=95% confidence interval. **Bold denotes significance**]

Follow-up year	Probability of SA days						Number of SA days					
	BB+A		BB		BB+A versus BB		BB+A		BB		BB+A versus BB	
	P	95% CI	P	95% CI	OR	95% CI	Mean	95% CI	Mean	95% CI	Ratio	95% CI
Total SA days												
1	0.70	0.5–0.9	0.80	0.6–0.9	0.60	0.2–2.1	12.6	6.8–23.8	14.6	7.9–28.0	0.9	0.5–1.6
2	0.80	0.6–0.9	0.80	0.7–0.9	0.70	0.3–1.8	13.1	6.2–26.6	10.0	5.1–19.9	1.3	0.6–3.0
3	0.70	0.6–0.9	0.70	0.5–0.8	1.20	0.5–3.0	14.3	7.0–26.1	14.3	7.1–28.0	1.0	0.4–2.2
4	0.70	0.5–0.9	0.60	0.4–0.8	1.50	0.4–4.9	18.8	10.2–35.2	25.2	13.9–50.2^a	0.7	0.4–1.4
LB-specific SA days												
1	0.20	0.1–0.3	0.20	0.1–0.4	0.80	0.5–1.3	11.7	6.2–21.5	8.4	4.9–14.8	1.4	0.8–2.5
2	0.10	0.1–0.2	0.20	0.1–0.3	0.80	0.5–1.4	8.1	4.7–14.6	5.8	3.4–10.2	1.4	0.8–2.5
3	0.10	0.1–0.2	0.10	0.1–0.2	0.80	0.4–1.4	8.8	5.2–15.5	6.3	3.7–11.0	1.4	0.8–2.5
4	0.10	0.0–0.2	0.10	0.1–0.2	0.80	0.5–1.4	13.3	7.4–25.7^b	9.6	5.4–18.1^c	1.4	0.8–2.5

^a Increase of SA days in time is significant between years 2 and 4 (P=0.030).

^b Increase of SA days in time is significant between years 3 and 4 (P=0.001).

^c Increase of SA days in time is significant between years 3 and 4 (P=0.001).

Table 4. Total and low-back (LB)-specific sickness absence (SA) periods in the BB+A (Back Book with advice) intervention and BB (Back Book) control groups. Probability (P) of SA periods that are >0 and odds ratio (OR) of the group comparison BB+A versus BB. The number of SA periods in the intervention groups and the Ratio of the group comparison BB+A versus BB. [95%CI=95% confidence interval]

Follow-up year	Probability of SA periods						Number of SA periods					
	BB+A		BB		BB+A versus BB		BB+A		BB		BB+A versus BB	
	P	95% CI	P	95% CI	OR	95% CI	Mean	95% CI	Mean	95% CI	Ratio	95% CI
Total SA periods												
1	0.70	0.5–0.9	0.80	0.7–0.9	0.50	0.1–1.8	2.40	0.9–5.4	2.10	0.9–4.8	1.1	0.4–2.8
2	0.70	0.6–0.8	0.80	0.7–0.9	0.70	0.3–1.4	1.90	1.2–3.1	2.00	1.3–3.1	1.0	0.5–1.7
3	0.70	0.6–0.8	0.70	0.5–0.8	1.30	0.6–2.8	1.90	1.2–3.3	2.80	1.7–4.6	0.7	0.4–1.3
4	0.70	0.5–0.9	0.60	0.4–0.8	1.70	0.5–5.9	2.40	1.0–6.2	3.90	1.7–9.7	0.6	0.2–1.6
LB-specific SA periods												
1	0.20	0.1–0.3	0.20	0.1–0.4	0.80	0.5–1.3	1.10	0.5–2.5	0.80	0.4–1.8	1.3	0.6–2.9
2	0.10	0.1–0.2	0.20	0.1–0.3	0.80	0.5–1.4	0.80	0.4–1.6	0.60	0.3–1.3	1.3	0.6–2.9
3	0.10	0.1–0.2	0.10	0.1–0.2	0.80	0.5–1.3	0.90	0.4–1.8	0.70	0.3–1.4	1.3	0.6–2.9
4	0.10	0.0–0.2	0.10	0.1–0.2	0.80	0.5–1.3	1.40	0.7–3.0	1.10	0.5–2.2	1.3	0.6–2.9

Discussion

The LB-specific patient information booklet with additional face-to-face information communicated by an OH nurse was not more effective on LBP, physical impairment, quality of life, or SA than the patient information booklet alone for a group of non-sick-listed employees, categorized as having mild LB symptoms after an employee survey.

Strengths and weaknesses of the study

Main strengths of this study lie at the pragmatic approach and the recruiting strategy of the subjects. All the employees at the company personnel were invited to participate in the questionnaire survey (N=2480).

The response rate was particularly high (71%). Patient information was delivered in a practical way by an occupational health (OH) nurse for employees with mild LB symptoms. In Finland, every OH unit has a nurse but not all have physiotherapists. Therefore, we assumed that LB-specific patient information should be delivered by an OH nurse, especially when the symptoms are minor. In the majority of previous studies on LBP, however, personal patient information has been provided by a physician. In some other fields of medicine, self-care has also been promoted by a nurse or other healthcare professional without losing the effectiveness of the intervention (35, 36).

We included employees who were generally healthy and able to continue working. They were not primarily seeking care but were expected to benefit from self-care

information for their LB symptoms. Employees had a history of LBP or ancillary symptoms for about 11–13 years and an average of 12 total SA days during one year prior to study inclusion, of which 1–2 days were LB specific. Most of them had a history of LB treatment, eg, a self-care program. According to study group characteristics and the pragmatic approach in this study, our results are most applicable in the OH setting. We believe that the study group was especially suitable for the trial on self-care information. We are not aware of other comparable studies in an OH setting.

All subjects received the intervention as intended and 74% of them continued to the final visit. Adherence to follow-up visits and response to the questionnaires was quite high throughout the two-year follow-up though some workers expected more intense treatment or rehabilitation for their LB trouble.

Personal, face-to-face information was performed with the help of a slide show, which was a complete review of the BB's content; no other information was included. The outcome variables have previously been validated and are widely used. Our SA data has good coverage, accuracy, and consistency (37) as salaries and other employee benefits are based on the same information. Still, our study may have been somewhat underpowered as regards SA variables, which can, for example, be seen from the broad CI in the differences between the treatment arms.

We chose well-described and validated LB-specific outcome variables in our study although they have been shown to function best in their mid-range (38). For example, RM-18 is rather insensitive to change when the impairment levels are low (39).

One reason for the lack of effectiveness might be that face-to-face information is rather a tenuous complement to the booklet information. Furthermore, it is not possible to exclude the possibility of group contamination since some of the employees in the BB group requested additional information on LBP during their follow-up visits. We have not systematically recorded or responded to these requests, but are aware that contamination to some extent is possible. All scheduled follow-up visits in this study should be considered as part of the intervention, but there were no differences between the groups in follow-up visit activity, intervals, or frequency. On the other hand, we made no systematic attempts to find out if the study subjects in the BB group actually read and understood the booklet. However, these facts originate from the pragmatic approach of the study, ie, these concerns cannot be ruled out in common practice either.

Comparison with previous studies

Educational booklets have been used in general practice and research purposes for many years. Results from

RCT on their effectiveness in LBP are mixed (3, 8, 11, 35, 40–44) and these prior studies have included patients with existing LB symptoms, either acute or chronic LBP. We are not aware of comparable RCT about LB-specific self-care information for non-sick-listed employees in an OH setting. There is an obvious need of evidence in this field.

The few prior RCT of non-sick-listed populations in an OH setting (45–48) have dealt with more intensive patient education and focused on general symptoms or risk of work disability. A population-based study in Denmark showed that a psychosocially oriented educational booklet without personal contact was not successful in reducing work absence due to general musculoskeletal pain (48). Interventions in two other studies (46, 47) were more intensive than provision of simple patient information and the study subjects were already at risk of work disability.

According to the recent Cochrane review, strong evidence supports that an individual 2.5-hour oral educational session is more effective on short- and long-term return to work than no intervention for patients that were absent from work due to acute or sub-acute LBP (9). Less-intensive interventions or written information alone were not effective, and there was no evidence of pain relief in these subjects. Another systematic review (13) concluded that simple patient information for subjects with chronic LBP increases patient knowledge about LBP and reduces pain, disability, and fear but not employee absenteeism. A positive result was strongly related to the personal contact between the information provider and the patient.

Obviously, the concept of self-care is quite different from the traditional care-giving concept in healthcare (49). Patients may gather patient information from various sources of their own choice and for their individual purposes. The quality of such information may range from non-factual to proper evidence-based information.

When OH professionals promote the self-care of LB patients, written information looks superior compared to oral information alone (3, 12, 50). On the other hand, we have found no effectiveness of the additional face-to-face information in our study. Like in some other studies (51–54), previous SA predicted future work loss also in this study. In the OH setting, there is an urgent need for simple and reliable LB-specific patient information that can be delivered to employees during their health surveillance visits. In the view of our findings, further research is needed to analyze the effectiveness of patient information compared to usual care in the secondary prevention of mild LB symptoms in the OH setting.

Concluding remarks

Face-to-face patient information, based on a LB-specific

booklet, was not more effective in combination with the booklet than the booklet information alone in reducing mild LB symptoms among non-sick-listed employees.

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