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Mini-Intervention for Subacute Low Back Pain

Two-Year Follow-up and Modifiers of Effectiveness

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Study Design. Randomized controlled trial.

Objectives. To investigate the long-term effectiveness, costs, and effect modifiers of a mini-intervention, provided in addition to the usual care, and the incremental effect of a worksite visit for patients with subacute disabling low back pain (LBP).

Summary of Background Data. A mini-intervention was earlier proved to be an effective treatment for subacute LBP. Whether the beneficial effect is sustained is not known. Furthermore, modifiers of a treatment effect are largely unknown.

Methods. A total of 164 patients with subacute LBP randomized into a mini-intervention (A, n = 56), a mini-intervention plus a worksite visit (B, n = 51), or the usual care (C, n = 57). Mini-intervention consisted of a detailed assessment of the patients' history, beliefs, and physical findings by a physician and a physiotherapist, followed by recommendations and advice. The usual care patients received the conventional care. Pain, disability, health-related quality of life, satisfaction with care, days on sick leave, and health care consumption and costs were measured during a 24-month follow-up. Thirteen candidate modifiers were tested for each outcome.

Results. There were no differences between the three treatment arms regarding the intensity of pain, the perceived disability, or the health-related quality of life. However, mini-intervention decreased occurrence of daily (A *vs.*, C, $P = 0.01$) and bothersome (A *vs.* C, $P < 0.05$) pain and increased treatment satisfaction. Costs resulting from LBP were lower in the intervention groups (A 4670 Euros, B 5990 Euros) than in C (C 9510 Euros) (A *vs.* C, $P = 0.04$; and B *vs.* C, not significant). The average number of days on sick leave was 30 in A, 45 in B, and 62 in C (A *vs.* C, $P = 0.03$; B *vs.* C, not significant). The perceived risk for not recovering was the strongest modifier of treatment effect. Mental and mental-physical workers in A and B were less often on sick leave than those in C.

Conclusions. Mini-intervention is an effective treatment for subacute LBP. Despite lack of a significant effect on intensity of low back pain and perceived disability, mini-intervention, including proper recommendations and advice, according to the "active approach," is able to reduce LBP-related costs. The perceived risk of not recovering was the strongest modifier of treatment effect. In alleviating pain, the intervention was most effective among the patients with a high perceived risk of not recovering. [Key words: subacute low back pain, randomized controlled trial, mini-intervention, worksite visit, sick leave, costs, outcome, modifier, subgroup] **Spine 2004; 29:1069–1076**

Low back pain is usually considered to be a benign and self-limiting condition.[1] However, returning to work is often difficult for patients with prolonged low back pain.[2] Low-cost interventions for such patients would thus be highly welcome and, in fact, simple interventions aimed at reducing fears have already been shown to reduce sick leave[3–5] among patients with subacute low back pain. At the subacute phase of low back pain, every effort should be made to prevent chronicity.[6] Evidence of effective interventions for subacute low back pain is, however, scanty[7–9] and evidence of how to prevent chronicity is even scantier.[10,11] Subgroup analyses within randomized controlled trials and identification of significant treatment modifiers could thus help to indicate the most beneficial interventions for patients with similar symptoms but different characteristics.

The aims of the present study were: 1) to investigate the long-term clinical effectiveness of the mini-intervention and the incremental effect of a worksite visit, and 2) to determine the most significant modifiers of the treatment effect regarding mini-intervention, mini-intervention with a worksite visit, and conventional care for patients with disabling low back pain that has lasted from 4 to 12 weeks.

Methods

Patients. Patients randomized into a mini-intervention group, a worksite visit group, or a usual care group were recruited from 36 primary health care centers in the Helsinki metropolitan area (Table 1). Inclusion criteria were as follows: 25- to 60-year-old employees with current daily low back pain (with or without sciatica), which had made working difficult for more than 4 weeks but less than 3 months.[5]

Randomization. Patients agreeing to participate were invited to one visit to the Finnish Institute of Occupational Health (FIOH). During this visit, the patients were asked to complete baseline questionnaires, after which the research nurse randomized each patient into one of the three study groups described below. A biostatistician had prepared the order from a

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Table 1. Baseline Characteristics of the Study Participants*

Characteristic	Mini-intervention Group (N = 56)	Worksite Visit Group (N = 51)	Usual Care Group (N = 57)
Demographic features			
Age (yr)	44 (25–60)	44 (25–60)	43 (25–59)
Females (%)	59	57	60
High school diploma (%)	41	28	33
Married (%)	43	49	42
Body mass index (kg/m^2)	27 (18–61)	27 (18–45)	25 (20–53)
Physical activity and general health			
Physical activity more than once a week before back pain (%)	75	67	79
Self-rated health status for age very or quite good (%)	100	96	95
Pain and disability†			
Patients having pain radiating below the knee (%)	69	69	68
Intensity of pain‡ (0–10)	6.2 (2–10)	5.4 (1–10)	5.7 (1–10)
Very or extremely bothersome pain during the past week (%)	79	77	79
Pain that interfered quite a bit or extremely with work or daily life during the past week (%)	79	67	68
Functional status			
Days on sick leave in the past 3 months	15.8 (0–70)	14.7 (0–50)	15.0 (0–69)
Oswestry disability index§	36 (4–69)	33 (7–71)	34 (13–67)
Work-related features			
Blue-collar workers (%)	20	22	25
Satisfaction with own work (0–10)‖	7.5 (0–10)	7.1 (0–10)	7.1 (2–10)
Ability to work (0–10)¶	5.4 (0–10)	5.4 (0–10)	5.3 (0–9)
Health-related quality of life			
15D**	0.85 (0.61–1.00)	0.86 (0.70–0.99)	0.86 (0.70–0.98)
Health care consumption during the past 3 months			
Visits to a physician	3.7 (0–20)	3.4 (0–12)	3.3 (0–18)
Visits to a physiotherapist	0.6 (0–8)	0.5 (0–6)	0.9 (0–12)
Satisfaction with overall medical care‖	4.5 (0–9)	4.2 (0–9)	4.1 (0–10)
Expectation of not recovering			
Subjective risk of not recovering (0–10)††	5.1 (0–10)	5.2 (0–10)	4.8 (0–10)

* Mean (range), unless otherwise stated. $P > 0.05$ on comparisons between the groups for each characteristic.
† Every patient had daily symptoms at baseline
‡ Scored on an 11-point ordinal scale, with 0 representing no pain at all and 10 unbearable pain.
§ Means as % of maximum score ([45]).
‖ Scored on an 11-point ordinal scale, with 0 representing complete dissatisfaction and 10 complete satisfaction.
¶ Scored on an 11-point ordinal scale, with 0 representing complete disability and 10 complete ability to work.
** Scale of 0.00–1.00, where 1.00 represents the best possible quality of life.
†† Scored on an 11-point ordinal scale, with 0 representing the best chance of recovering and 10 the highest risk of not recovering.

random number table. A secretary without any connection with the patients had numbered the envelopes sequentially to prevent their rearrangement. The research nurse and researchers were not aware of the block size and so could not predict the group assignments.[5]

Interventions

Mini-Intervention Group (Group A). The mini-intervention was based on current guidelines,[12–15] including features from two trials[4,16–18] reported earlier. The specific exercises recommended were based on studies of the function and well-being of the back.[19–21] A physician first interviewed and examined the patients in the mini-intervention group (n = 56) and encouraged them to ask about anything unclear concerning their back pain. Working conditions were discussed, the results of the clinical examination explained to the patients, and the radiograph findings and causes of pain clarified as far as possible. Misunderstandings were corrected according to current knowledge.

The physician then introduced the patient, with the main clinical findings and the radiographs, to a senior specialist physiatrist as well as to a physiotherapist, who confirmed the diagnosis and informed the patient of the good prognosis of the disorder and the importance of avoiding bed rest, remaining active, and exercising daily (walking, bicycling, skiing, *etc.*). Sick leave was prescribed, if necessary. The patient, both physicians, and the physiotherapist together mutually planned the best ways for the patient to cope with the back pain.

The main aim of these consultations was to reduce the patients' concerns about their back pain by providing accurate information and to encourage physical activity. The first part of these consultations typically lasted for 45 minutes, the latter part for 15 minutes. After this, the patient and the physiotherapist together appraised the patient's daily back-straining activities, such as lifting, sitting, standing, sitting down and standing up, walking, and reaching out, sleeping position, and housework, with the aim of increasing body control and exercising in everyday life. Special movements required at the patient's work were practiced if necessary. On the basis of individual need and motivation, the physiotherapist instructed the patient a maximum of five exercises for improving the function of the deep abdominal muscles and establishing symmetric use of the back. Other daily exercises were planned so that it was feasible for the patient to commit himself/herself to carrying them out. The consultation with the physiotherapist lasted for approximately 1.5 hours.

A physician sent a feedback (including recommendations about further diagnostic tests, treatment, work, and sick leave) to the patient's general practitioner, who was subsequently in charge of treatment. The general practitioner at the patient's

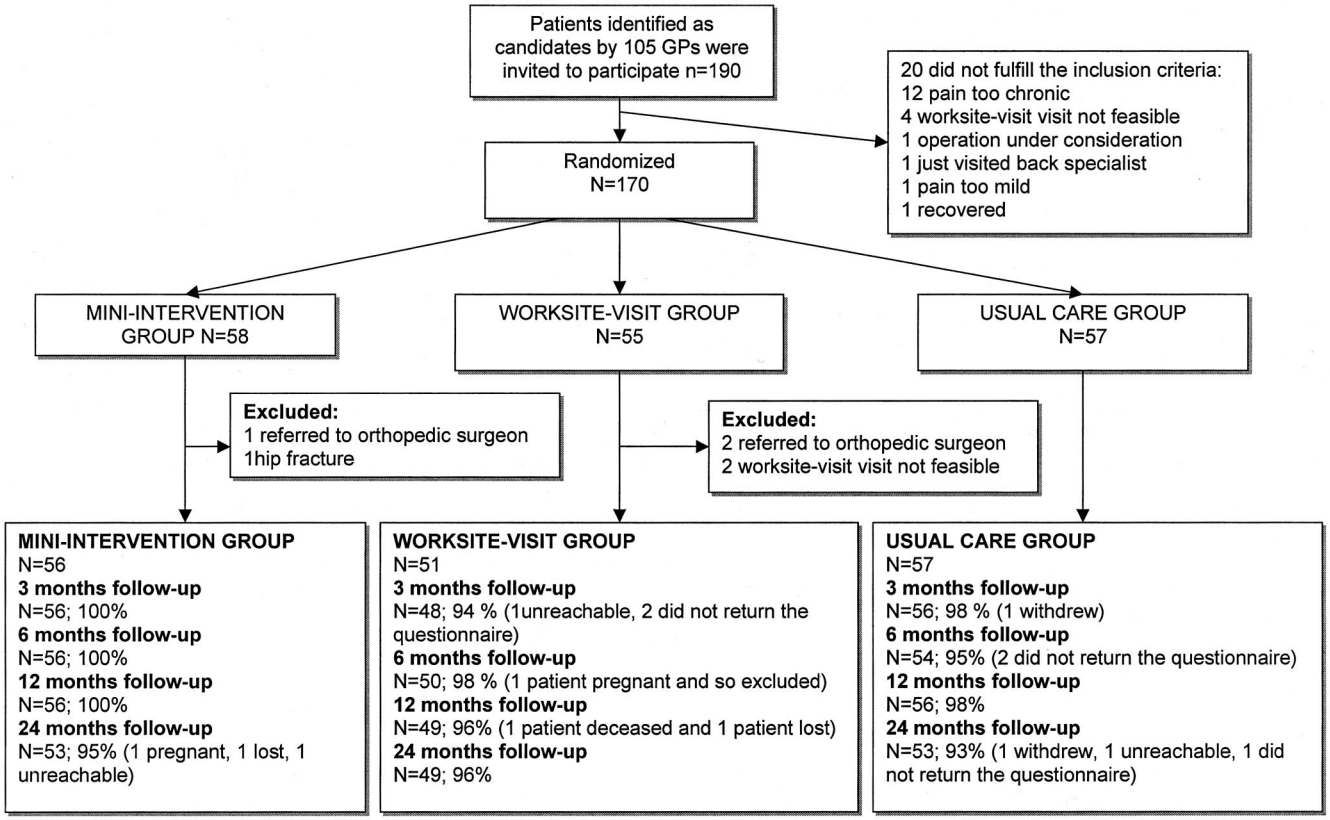

Figure 1. Patient flow during the study.

local primary health care center coordinated the recommended treatment in his/her usual manner at the health care center.

Worksite Visit Group (Group B). Intervention for the worksite visit group at FIOH (n = 51) was identical to that for Group A and performed without knowledge of the final group assignment (worksite visit or not), which the research nurse confirmed just before the patient left FIOH. The physiotherapist visited the patient's worksite shortly after the FIOH appointment or his/her return to work. The patient's work supervisor, the company nurse, a physiotherapist, and an occupational physician were asked to join in the session. The aim of the worksite visit, which lasted for approximately 75 minutes, was to ensure that the patient had adapted to the information and practical instructions of appropriate ways of using his/her back at work, to involve the supervisor and company healthcare professionals, and to encourage their cooperation. If needed, the patient was given additional advice on back-friendly working techniques. Routine suggestions about the purchase of specific equipment for the worksite or the working environment were avoided.

A physician sent a feedback from the FIOH visit and a physiotherapist sent a written report describing the substance and findings of the worksite visit to the patients' company physicians and general practitioners. The other participants in the worksite visit were sent only a report describing the worksite visit. The patient was encouraged to continue cooperation with the company healthcare experts. The company physician was advised to refer any patient with disabling low back pain or who was still on sick leave 3 months after randomization for inpatient rehabilitation to the ORTON Rehabilitation Center in Helsinki.

Usual Care Group (Group C). Patients in the usual care group (n = 57) were not examined at FIOH but received a leaflet on back pain[22] (as did all the other study patients). They were treated by their general practitioners in primary health care in the usual manner, including specialist consultations, physiotherapy, *etc.*, when necessary. They were not discouraged from seeking specialist treatment privately, *i.e.*, at their own expense, if they so wished.

Follow-up. Patients in each study group were followed up by questionnaires 3, 6, 12, and 24 months after randomization (Figure 1).

Outcomes. The main outcomes were the self-rated intensity of low back pain (on an ordinal scale of 0 to 10), the frequency and bothersomeness of the pain, the interference of the pain with daily life,[23] the perceived disability (Oswestry),[24] the health-related quality of life (15D),[25] the overall satisfaction with the care (on an ordinal scale of 0 to 10), healthcare consumption and costs, and the back pain-related sick leave.

Statistics. Power calculations were carried out before the study to attain a power at least equal to 0.80 at the 0.05 significance level on the intensity of pain (on a scale of 0 to 10); 45 patients per group and a total of 135 subjects were needed.

Intention-to-Treat Analysis. Patients were included in the analysis on the basis of their intervention group allocation. A structured method for analysis of repeated measures was used to analyze the continuous response data (*i.e.*, repeated observations at follow-up times of 3, 6, 12, and 24 months). The

Table 2. Results at 3-, 6-, 12-, and 24-Month Follow-ups*

Variable	Follow-up (mo)	Mini-intervention Group (A)	Worksite Visit Group (B)	Usual Care Group (C)	A − C	B − C
Intensity of pain†‡	3	4.1 (0–9)	3.5 (0–10)	4.1 (0–9)		
	6	3.7 (0–8)	3.6 (0–8)	3.7 (0–10)	−0.07 (−0.79–0.65)	−0.10 (−0.84–0.64)
	12	3.8 (0–8)	3.2 (0–9)	3.7 (0–10)	$P = 0.857$	$P = 0.781$
	24	3.5 (0–9)	3.2 (0–9)	3.4 (0–9)		
Daily symptoms§	3	18%	19%	38%		
	6	13%	18%	25%	0.39 (0.19–0.79)	0.52 (0.26–1.02)
	12	4%	8%	13%	$P = 0.009$	$P = 0.059$
	24	15%	16%	17%		
Very or extremely bothersome pain during the past week§	3	29%	35%	48%	0.55 (0.30–0.99)	0.71 (0.38–1.32)
	6	20%	26%	34%	$P = 0.048$	$P = 0.284$
	12	20%	27%	29%		
	24	23%	20%	29%		
Pain has interfered quite a bit or extremely with work or with daily life during past week§	3	25%	25%	35%	0.59 (0.31–1.13)	0.54 (0.28–1.06)
	6	16%	22%	34%	$P = 0.115$	$P = 0.076$
	12	14%	10%	23%		
	24	21%	10%	17%		
Oswestry disability index†‖	3	20 (0–44)	22 (0–78)	25 (0–76)		
	6	19 (0–56)	19 (0–53)	21 (0–51)	−2.02 (−6.51–2.47)	−0.42 (5.02–4.18)
	12	19 (0–62)	18 (0–62)	19 (0–51)	$P = 0.376$	$P = 0.857$
	24	19 (0–60)	18 (0–60)	18 (0–58)		
15D†¶	3	0.889 (0.7–1.0)	0.888 (0.6–1.0)	0.870 (0.6–1.0)		
	6	0.900 (0.6–1.0)	0.891 (0.6–1.0)	0.888 (0.7–1.0)	0.012 (0.009–0.033)	0.003 (0.019–0.024)
	12	0.881 (0.6–1.0)	0.888 (0.6–1.0)	0.892 (0.7–1.0)	$P = 0.260$	$P = 0.802$
	24	0.896 (0.7–1.0)	0.891 (0.49–1.0)	0.885 (0.6–1.0)		
Satisfaction with medical care (0–10)†**	3	6.2 (1–10)	6.1 (0–10)	4.1 (0–10)		
	6	5.9 (0–10)	6.4 (0–10)	4.3 (0–10)	1.53 (0.65–2.40)	1.96 (1.05–2.86)
	12	5.9 (0–10)	6.7 (0–10)	4.1 (0–10)	$P = 0.001$	$P = 0.000$
	24	5.8 (0–10)	6.2 (0–10)	4.3 (0–10)		
Days on sick leave††	24	30 (0–615)	45 (0–610)	62 (0–630)	0.030	0.133
Costs due to low back pain (Euro)‡††	24	4673 (152–81112)	5988 (209–80151)	9512 (0–80773)	0.043	0.053

* At 3 months, A (n = 56), B (n = 48), and C (n = 56); at 6 months, A (n = 56), B (n = 50), and C (n = 54); at 12 months, A (n = 56), B (n = 49), and C (n = 56); at 24 months, A (n = 53), B (n = 50), and C (n = 53); if not otherwise stated.
† Mean (range). The between-group significance, estimate (95% confidence interval) and *P* value, has been calculated for the entire follow-up period using the repeated-measures analysis with a baseline and time factor.
‡ Scored on an 11-point ordinal scale, with 0 representing no pain at all and 10 unbearable pain.
§ Dichotomous outcome. Percentages in each group. The between-group significance, odds ratio (95% confidence interval) and *P* value, has been calculated for the entire follow-up period, using the repeated-measures analysis with a baseline and a time factor.
‖ Mean % of maximum score (45).
¶ Scale of 0.00–1.00; 1.00 represents the best possible quality of life.
** Scored on an 11-point ordinal scale, with 0 representing complete dissatisfaction and 10 complete satisfaction.
†† Mean (range). Statistical significance (*P* value) of cumulative days on sick leave during the 2-year follow-up after randomization was calculated only for patients who returned all follow-up questionnaires. Sick leave was not controlled for with the baseline findings: A (n = 55), B (n = 46), and C (n = 51).
‡‡ During the 2-year follow-up, the mean (range) of costs of visits to physicians, physiotherapists, and nurses, days in inpatient care in hospital, rehabilitation, diagnostic tests, x-rays and medication, and days on sick leave (130 Euro per day): A (n = 49), B (n = 45), and C (n = 48).

group comparisons were analyzed with a model, including the time factor and baseline information, using the mixed procedure of the SAS system. For binary responses, we used the Generalized Estimating Equations method to analyze our repeated measures data; with this method, the mean response is modeled as a logistic regression model with the odds ratio as the effective measure. For the economic analysis, the use of medication and healthcare services was recorded by questionnaires. Costs were based on market prices where possible or on information from the health services producers. The total costs were analyzed, using the human capital method.[26] The Kruskal-Wallis nonparametric method was used to analyze costs due to low back pain and days on sick leave (Table 2).

Subgroup Analysis. The modifying effect of candidate modifiers (baseline factor) was studied by adding the interaction term of the modifier with the intervention variable into the model. When performing subgroup analyses, the utilization of the interaction term enabled the inclusion of the entire data instead of the just the data on the subgroup under consideration at the time. For the binary and the continuous response variables, the repeated methods described earlier were used. For the data on costs, the usual regression method with log transformation for the response variable was used. For the data on sick leave, the ordinal logistic regression method was used when the original response variable was categorized into two categories. In the preliminary Phase 1 analysis, all intervention comparisons were done repeatedly for each modifier (Tables 3 and 4, available for viewing on Article Plus). Then the interaction considering the three treatment options was studied. In Phase 2, those modifiers having significant ($P < 0.05$) interaction on any of the assessed nine outcomes were selected for the final multivariate analysis (Table 5).

Ethical Considerations. The Ethical Committees of the FIOH and the three participating cities approved the study. Patient information was provided according to the Declaration of Helsinki.[5,27]

Table 5. Modifying Factors in Multivariate Analysis*

Candidate Modifier	Intensity of Pain (0–10)†	Daily Symptoms	Bothersome Pain	Pain Interfering With Work or Daily Life	Oswestry Disability Index‡	HRQL (15D)§	Satisfaction With Medical Care (0–10)‖	Total Costs (€)¶	Sick Leave (0–4, 5–29, or >29 days)**
Type of work††	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	0.023
Sick leave due to current low back pain episode‡††	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Intensity of pain at baseline§§	n.s.	n.s.	0.038	0.037	n.s.	n.s.	n.s.	n.s.	n.s.
Oswestry disability index‖‖	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Perceived risk of not recovering¶¶	0.048	0.008	0.016	0.002	0.014	n.s.	n.s.	n.s.	n.s.

* Significance of modifying effect expressed with *P*-value; n.s. (nonsignificant, $P \geq 0.05$). Candidate modifiers are dichotomized. At 3 months, A (n = 56), B (n = 48), and C (n = 56); at 6 months, A (n = 56), B (n = 50), and C (n = 54); at 12 months, A (n = 56), B (n = 49), and C (n = 56); at 24 months, A (n = 53), B (n = 50), and C (n = 53), if not otherwise stated.
† Scored on an 11-point scale, with 0 representing no pain at all and 10 unbearable pain.
‡ Back-specific functional disability measured with the Oswestry Disability Index (0–100).
§ Health-related quality of life measured with 15D. Scale of 0.00–1.00; 1.00 represents the best possible quality of life.
‖ Scored on an 11-point scale, with 0 representing complete dissatisfaction and 10 complete satisfaction.
¶ During 2-year follow-up, mean (range) of costs of visits to physicians, physiotherapists, and nurses, days in inpatient care in hospital, rehabilitation, diagnostic tests, x-rays and medication, and days on sick leave (130 Euro per day): A (n = 49), B (n = 45), and C (n = 48).
** Cumulative days on sick leave distributed (0–4, 5–29, or >29 days). Cumulative days on sick leave after randomization was calculated only for patients who returned all follow-up questionnaires. Sick leaves were not controlled for with the baseline findings: A (n = 55), B (n = 46), and C (n = 51).
††Physical or lighter (mental and mental-physical).
‡‡Yes or no.
§§ Dichotomized ordinal scale 0–5 or 6–10, with 0 representing no pain at all and 10 unbearable pain.
‖‖ 0–40 or 41–100.
¶¶Dichotomized ordinal scale 0–5 or 6–10, with 0 representing best change of recovering and 10 highest risk of not recovering.

■ Results

Study Population

Between August 1998 and May 2000, 164 patients were enrolled in the trial. Figure 1 shows the patient flow and the reasons for exclusions. At baseline, the patients in each treatment arm were comparable (Table 1).

Interventions and Cointerventions

The physiotherapist visited 49 worksites of the 51 patients in the worksite visit group;[5] two patients needed to change their jobs owing to back pain, and in these cases such visits were not made.

Two patients in Groups A and B and three in Group C had spinal surgery during the 24-month follow-up. Cointerventions such as other healthcare visits (including the use of alternative medicine services) were equally distributed among the three groups.

Outcomes

During the 24-month follow-up, the patients in the intervention groups spent clearly fewer days on sick leave (average number of days on sick-leave 30 days in the mini-intervention group, 45 days in the worksite visit group, and 62 days in the control group) (A *vs.* C, $P = 0.030$, B *vs.* C, not significant) (Table 2; Figure 2).

The number of patients suffering from daily pain was smaller ($P = 0.009$) and the pain was less bothersome ($P = 0.048$) in the mini-intervention group than in the usual care group (Table 2). However, there were no clinically or statistically significant differences between the three treatment arms regarding the intensity of pain, the perceived disability, or the health-related quality of life (Table 2).

During the follow-up, the patients in the two intervention groups were more satisfied with their medical care than those in the usual care group (A *vs.* C, $P = 0.001$ and B *vs.* C, $P = 0.000$) (Table 2).

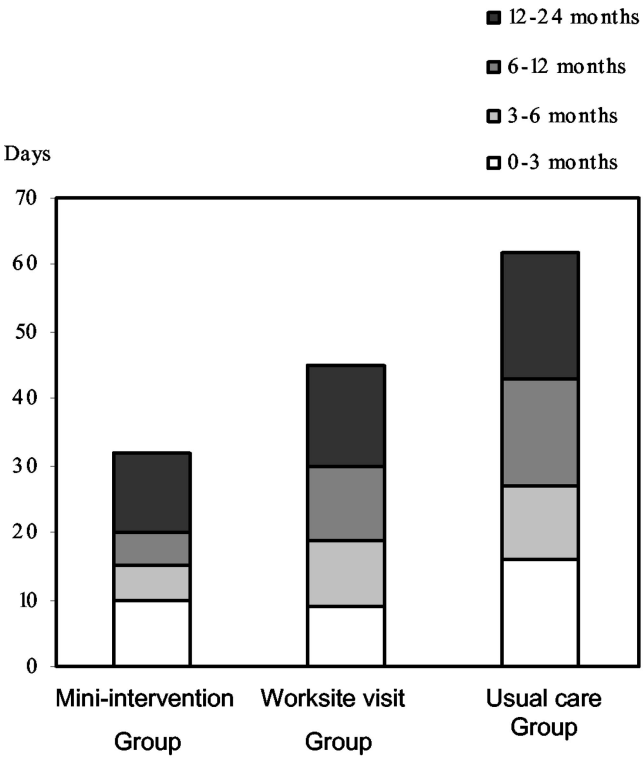

Figure 2. Cumulative days on sick leave during the 24-month follow-up.

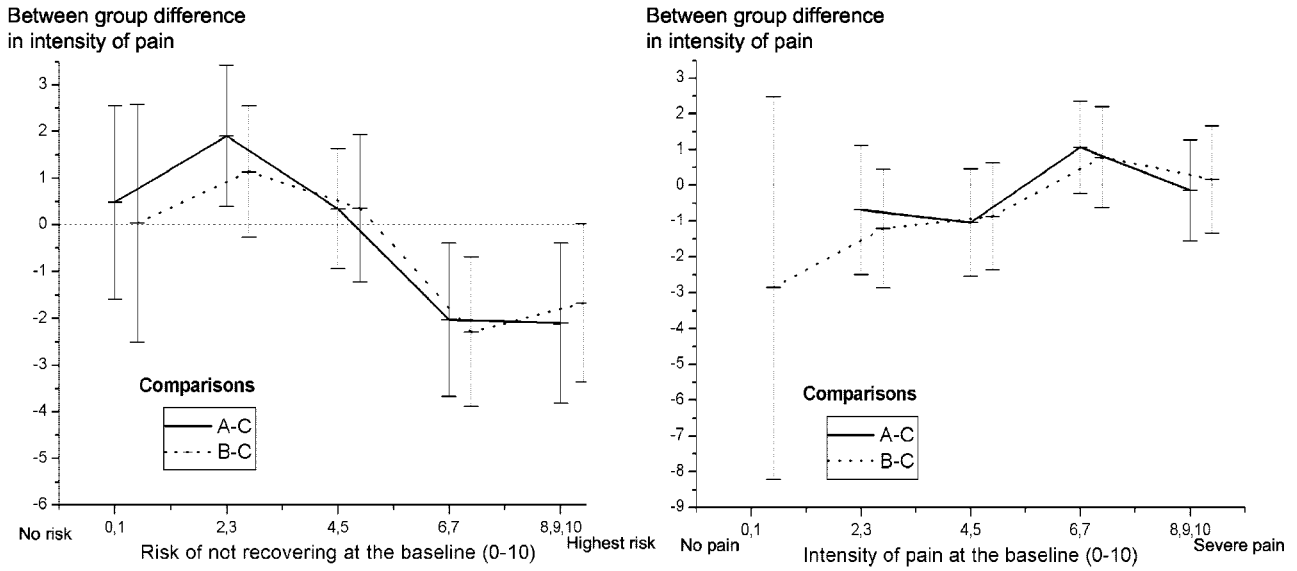

Figure 3. Perceived risk of not recovering and intensity of pain before treatment, as modifiers of treatment effect on intensity of pain during the 2-year follow-up. Between-group difference with 95% confidence intervals. Negative values stand for effectiveness in favor of the interventions A (mini-intervention group) and B (worksite visit group) compared with C (usual care).

Health Care Consumption and Costs

On average, the patients in all three groups had a comparable number of visits to physicians, physiotherapist, and nurses during the 2-year follow-up. In the mini-intervention group, only 1 patient had been in inpatient rehabilitation as compared with 7 patients in the usual care group and 4 in the worksite visit group (A *vs.* C, $P = 0.022$; and B *vs.* C, P = not significant). The direct health care costs were, on average, 583 Euros smaller in the mini-intervention group and 512 Euros smaller in the worksite visit group than among the controls (not statistically significant). Total costs related to low back pain (costs of sick leave and direct healthcare costs) were 4,839 Euros smaller in the mini-intervention group and 3,524 Euros smaller in the worksite visit group than in the usual care group (A *vs.* C, $P = 0.043$; B *vs.* C, P = not significant; Table 2).

The two intervention groups (A *vs.* B) did not differ from each other in a statistically or clinically significant manner in any of the clinical or economic outcomes.

Treatment Modifiers

Modifying Effect of Separate Baseline Factors (Phase 1). Considering all three treatment options, any previous sick leave ($P = 0.045$), the intensity of pain ($P = 0.013$), the Oswestry disability index ($P = 0.016$), and the perceived risk of not recovering ($P = 0.006$) at the baseline modified the outcome "intensity of pain" during the 2-year follow-up. The perceived risk of not recovering was the only significant factor modifying the outcomes "occurrence of daily symptoms" ($P = 0.038$) and "perceived disability (OSW)" ($P = 0.015$). The intensity of pain ($P = 0.005$) and the perceived risk of not recovering ($P = 0.042$) modified the bothersomeness of pain. The intensity of pain ($P = 0.010$) and the perceived risk of not recovering ($P = 0.026$) also modified the occurrence of pain interfering with work or with daily life. There were no significant modifiers of health-related to quality of life (15D) or to satisfaction with medical care. The only factor modifying total health care costs ($P = 0.047$) and accumulation of sick leave days during the 2-year follow-up ($P = 0.027$) was the type of work.

Regarding the comparison between the mini-intervention and usual care, Table 3 shows the magnitude of the modifying effect separately for the 13 potential modifiers. The respective comparison between the worksite visit group and usual care is presented in Table 4.

Expectations regarding the effectiveness of treatment or self-rated health status for age did not significantly modify any of the nine treatment outcomes.

Modifying Effect in Multivariate Analysis (Phase 2). Five candidate modifiers with a significant interaction term were selected for the multivariate analysis. Table 5 shows that the subjective risk of not recovering (measured before treatment allocation) is the most important modifier of the treatment effect.

Considering the intensity of the pain during the 2-year follow-up, the perceived risk of not recovering modifies the effect of the treatment more than the intensity of pain itself at baseline (Figure 3). The intensity of the pain among patients with a low perceived risk of not recovering (2 or 3 on the scale of 0–10) was higher in the mini-intervention group than among controls during the 2-year follow-up (A *vs.* C, 1.9 ± 0.76 [SE], $P = 0.01$). In contrast, the intensity of the pain among patients with a high perceived risk of not recovering (6 or 7 in scale of 0–10) was milder in the mini-intervention and mini-intervention plus worksite visit groups than among con-

trols during the 2-year follow-up (A *vs.* C, −2.0 ± 0.82 [SE], $P = 0.01$; and B *vs.* C, −2.3 ± 0.80 [SE], $P < 0.01$).

■ Discussion

Our results show that a detailed but still relatively brief (2.5-hour) mini-intervention by a physiatrist and physiotherapist reduces sick leave (Figure 2) and back pain-related costs and has a long-lasting positive impact on the patients' symptoms and satisfaction with medical care. However, an additional worksite visit does not improve the clinical outcome. Both the mini-intervention and the mini-intervention plus worksite visit lead to greatest effectiveness among patients with a high perceived risk of not recovering. As the mini-intervention and the worksite visit were the only additions to usual care in the intervention groups of our study, we can confidently say that an early consultation with a specialist has a positive impact on recovery from subacute low back pain. The three strengths of our study are the simple design of the trial, the high follow-up percentage (94%–100%) in each group, and the sufficiently long follow-up. The fact that the mini-intervention and the incremental worksite visit can easily be reproduced elsewhere suggests that our results can be generalized to back pain patients of other countries as well.

The direct healthcare costs of the patients in the mini-intervention group turned out to be clearly (although not statistically significantly) lower than those the of the usual care group. The cost-saving potential of the mini-intervention was even more evident when the costs of sick leaves were also taken into account. In the light of these results, it seems possible that, by investing a little more in the early efficient intervention and treatment of subacute low back pain, considerable long-term savings can be expected.

Perceived risk and type of occupation were the most important modifiers of the treatment effect, when comparing the mini-intervention and the mini-intervention plus worksite visit with the usual care. Among mental and mental-physical workers in the mini-intervention and the worksite visit groups, the days on sick leave was lower than in the usual care group. Blue-collar workers did not benefit significantly more from either treatment scheme as compared with usual care. A more intensive worksite visit could perhaps have improved the effect of treatment also among the blue-collar workers, but at the moment this remains speculative and further research is clearly indicated. According to our results, it seems worthwhile if in clinical practice patients' beliefs about recovering were appraised and used for subsequent treatment decisions. The patients who believe that they will recover can perfectly well be treated in primary care, but those with a higher perceived risk of not recovering may need time, more accurate information, answers for questions, and simple instructions about how to cope with nonspecific back pain. A mini-intervention provides a simple and effective way of helping these patients and spares them from expensive cognitive-behavioral treatments. In our study, mental or mental-physical workers in both the mini-intervention and the worksite visit groups were encouraged to continue working despite pain. This proved to be successful and was reflected in lower back pain-related costs in these patients. Findings like this can assist clinicians to focus the available treatments for the right patients. Advanced analysis of modifying factors can improve the quality of randomized controlled trials[28] by moving from an average patient of the group toward an individual with specific characteristics. The results of randomized trials are recognized as the golden standard of efficacy. Therefore, it should be viewed as an ethical obligation to try to extract data concerning subgroups that do not benefit from specific treatments from such trials. Interaction tests can recognize the limited extent of data available for subgroup analysis and provide the most effective statistical tool for avoiding false or premature claims regarding subgroup findings.[28]

■ Conclusion

Despite lack of a significant effect on intensity of low back pain and perceived disability, a mini-intervention performed by a physician specialized in back pain together with a physiotherapist, and involving clinical examination, information, support and simple advice, reduced absenteeism from work due to pain, daily symptoms, and costs related to low back pain. The intervention also led to better treatment satisfaction and adaptation to pain as compared with the usual care in patients with subacute low back pain. Although the mini-intervention slightly increased the initial treatment costs, it led to substantial savings in long-term healthcare spending. An additional worksite visit, however, did not improve the beneficial clinical or financial effect of the intervention. The perceived risk of not recovering was the strongest modifier of treatment effect. Among patients with a high perceived risk of not recovering, both the mini-intervention and the mini-intervention plus worksite visit led to more favorable results regarding pain-related outcomes than the usual care alone. Among mental or mental-physical workers, both the mini-intervention and the mini-intervention plus worksite visit reduced days on sick leave as compared with the usual care.

■ Key Points

- For patients with subacute low back pain, teamwork of a physiatrist and a physiotherapist, in the form of a mini-intervention involving clinical examination, information, support, and simple advice, reduces daily symptoms and work absenteeism and increases treatment satisfaction and adaptation to pain.

- Mini-intervention, as part of the regular treatment for subacute low back pain, reduces costs.
- A worksite visit does not appear to add to the clinical effectiveness of the mini-intervention.
- Perceived risk of not recovering is the strongest modifier of treatment effect in the present study.
- Mini-intervention leads to the greatest effectiveness among patients with a high perceived risk of not recovering.

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