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Cost-effectiveness of Combined Manipulation, Stabilizing Exercises, and Physician Consultation Compared to Physician Consultation Alone for Chronic Low Back Pain: A Prospective Randomized Trial With 2-Year Follow-up

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Study Design. A prospective, randomized controlled trial.

Objective. To examine long-term effects and costs of combined manipulative treatment, stabilizing exercises, and physician consultation compared with physician consultation alone for chronic low back pain (cLBP).

Summary of Background Data. An obvious gap exists in knowledge concerning long-term efficacy and cost-effectiveness of manipulative treatment methods.

Methods. Of 204 patients with cLBP whose Oswestry Disability Index (ODI) was at least 16%, 102 were randomized into a combined manipulative treatment, exercise, and physician consultation group (*i.e.,* a combination group), and 102 to a consultation alone group. All patients were clinically examined, informed about their back pain, and encouraged to stay active and exercise according to specific instructions based on clinical evaluation. Treatment included 4 sessions of manual therapy and stabilizing exercises aimed at correcting the lumbopelvic rhythm. Questionnaires inquired about pain (visual analog scale [VAS]), disability (ODI), health-related quality of life (15D Quality of Life Instrument), satisfaction with care, and costs.

Results. Significant improvement occurred in both groups on every self-rated outcome measurement. Within 2 years, the combination group showed only a slightly more significant reduction in VAS ($P = 0.01$, analysis of variance) but clearly higher patient satisfaction ($P = 0.001$, Pearson χ^2) as compared to the consultation group. Incremental analysis showed that for combined group compared to consultation group, a one-point change in VAS scale cost $512.

Conclusions. Physician consultation alone was more cost-effective for both health care use and work absenteeism, and led to equal improvement in disability and health-related quality of life. It seems obvious that encouraging information and advice are major elements for the treatment of patients with cLBP.

Key words: low back pain, randomized controlled trial, spinal manipulation, cost-effectiveness. **Spine 2005;30: 1109–1115**

In Finland, chronic low back pain (cLBP) and mental depression are the 2 most common complaints leading to work loss and early retirement. An increasing trend in sick leave because of low back disability has been perceived in most western societies. Despite the enormous developments in modern medicine in general and growing knowledge of spinal diseases, we have been unable to solve the problem of nonspecific low back pain (LBP). A better understanding of biopsychosocial aspects may have brought us closer to a solution.

An effective treatment method should improve the patient's quality of life and lead to cost savings both for the patient and society.[1] Its effectiveness should be supported by significant positive results derived from a randomized controlled trial (RCT),[2] and the effects should be long-lasting. In addition, the treatment should be well accepted by patients. Of the numerous studies dealing with spinal manipulation, only a few RCT exist with at least a one-year follow-up.[3–8] Of these studies, only Skargren *et al*[7] and Hemmila[9] included analysis of both direct and indirect costs at one-year. Cherkin *et al*[5] assessed direct costs at the 2-year follow-up, and Burton *et al*[4] at 1 year. Hemmila[9] included an instrument to assess generic functional status to make the results more generalizable and comparable to those of other studies.[1] An obvious gap exists in knowledge concerning long-term efficacy and cost-effectiveness of manipulative treatment methods combined with advice and exercise.

Our prospective RCT of combined spinal manipulation, stabilizing exercises, and physician consultation compared to physician consultation alone found the manipulative treatment with special exercises more effective for reducing pain and disability in patients with cLBP at 1 year.[10] Both treatment arms reduced pain, subjective

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disability, and depression, and increased health-related quality of life (HRQOL).

The aim of the present study was to compare the 2-year effectiveness and cost-effectiveness of these 2 treatment arms with special reference to the assessment of HRQOL. Our hypothesis was that spinal manipulation with stabilizing exercises directed at increasing motor control and balance, plus information from a physician, would reduce pain and disability, increase HRQOL, and save costs (in decreasing the work absenteeism and the use of health care) more at 2 years than would the latter one with physician information, advice, encouragement, and individual exercise instruction.

■ Patients and Methods

Study Population. The study included 24 to 46-year-old employed subjects with cLBP (with or without sciatica), whose Oswestry Disability Index (ODI) was at least 16%. Exclusion criteria were previous spinal operation, severe sciatica in the straight-leg-raising test with less than 35°, or weakened general condition, such as an inflammatory or malignant state or recent vertebral fracture, for which manipulation is contraindicated.

Interventions

Combined Manipulation/Exercises/Information Group (combination group). Patients in this group attended one-hour evaluation, treatment, and exercise sessions once weekly for 4 weeks. The therapy included manipulation using a muscle-energy technique and motor control (*i.e.,* stabilizing) exercises aimed at correcting the lumbopelvic rhythm. Stabilizing exercises were taught by asking the patients to draw in the stomach while receiving verbal, visual, and tactile feedback, meanwhile measuring pressure change with a biofeedback meter. Gradually, the patients were instructed to perform the stabilizing exercises in a more functional manner. Finally, they learned to do these isometric exercises during their daily activities.

Physician Consultation Alone Group (consultation group). Both the combination and consultation groups were examined clinically, with all clinical and radiograph findings explained to them, and possible causes of pain clarified. Each patient received an educational booklet, and individual instructions regarding posture and 3−4 exercises aimed at increasing spinal mobility, muscle stretch, and/or trunk muscle stability based on the clinical evaluation to encourage patients to be active instead of undergoing passive treatments. At the 5-month follow-up, this information was reinforced.

Outcome Measures. The outcomes were pain intensity, back specific disability, HRQOL (15D Quality of Life Instrument [15D]), days of sick leave, costs of health care consumption, productivity costs, and satisfaction with care. The degree of pain and disability was quantified by: (1) a visual analog scale (VAS) (range 0–100); (2) frequency of LBP; and (3) the ODI (range 0–100).

Subscales of the 15D (HRQOL) of the 2 study groups were compared to those of average 24- to 54-year-old Finns (data on a normal population described by Arinen *et al.*[11]). The questionnaires were presented at the initial examination before randomization, at 5-month follow-up examination, and at 12 and 24 months after randomization.

Both direct and indirect costs were assessed. Costs were assessed from a societal perspective. The use of health services, direct drug and traveling costs to the patients, and productivity costs as a result of absence from work were measured by a questionnaire for the study population before randomization, and at 12 and 24-month follow-up. Service fees from the patients were not included in cost analysis. For monetary valuation of health services, we applied Finnish standard cost information at the 2000-year price level.[12] Standard costs are average costs for various specified procedures or diagnostic tests by representative Finnish health care providers. Productivity costs were valued by the average 2000-year wage level in Finland. Because of theoretical and methodological controversy surrounding such valuation, we tested the effect of the valuing algorithm on total costs by using a 50% lower estimate of the average wage level. Costs were converted into the American dollar ($) ($1 = 1.01 Euro 9/2002). The costs or effects were not discounted. Although there were no differences in the temporal generation of costs, the discount rate had no significance between the groups.

Statistical Analysis. Missing values in questionnaires were substituted with previous after-treatment value (*i.e.,* last value carried forward technique). However, in cost analysis, missing values were interpreted as being zero if there simultaneously were markings in cost items elsewhere. Continuous outcomes were analyzed according to the intention-to-treat principle, with repeated measures analysis of variance (ANOVA) (group × time of assessment). In case of skewed distribution of the data, logarithmic or square root transformation was used. Comparison of proportions between the groups was performed using the Pearson χ^2 test. The Mann-Whitney test was used to compare the work absenteeism at baseline between the groups. Heterogeneity of the changes within groups was tested with the McNemar χ^2 test. Cost-effectiveness estimates were constructed for 2 main outcomes: pain and functional status. Statistical tests for cost-effectiveness ratios were accomplished using the bootstrapping technique, in which 5000 simulated replica data were formed. Bootstrapping was used to assess uncertainty around point estimates of incremental costs, effectiveness, and cost-effectiveness, which were derived from the study sample. Data were analyzed with SYSTAT 10 (Systat Software, Inc., Point Richmond, CA) for Windows software (Microsoft Corp., Redmond, WA). Bootstrapping and tests of the incremental cost-effectiveness ratio were performed using R 2.0.1 software (The R Foundation for Statistical Computing, Version 2.0.1. www.r-project.org). Significance was accepted at the 5% level. The 2-tailed test was applied for all *P* values.

■ Results

Participant Flow and Follow-up

A patient sample of 210 was selected on the basis of anamnestic criteria from 900 volunteers. After the physician's examination, 204 patients were included in the trial. A total of 102 patients were assigned randomly to the combination group and 102 to the consultation group. All patients visited the physician at least once before randomization. Of the subjects, 94% in the combination group and 92% in the consultation group visited the physician for the second examination. All subjects assigned to the combination group visited the manual therapist at least once.

Table 1. Outcomes Among the Subjects in the Combination and Consultation Groups*

Outcome Measure	Time Point (mos)	Combination Group	Consultation Group	*P* Value for Time Effect¶	*P* Value for Time Group Interaction¶
VAS (mm)†	0	58.6 (21.8) (N = 102)	53.9 (20.7) (N = 101)		
	5	25.3 (22.8) (N = 100)	35.7 (23.6) (N = 101)		
	12	26.0 (21.9) (N = 96)	32.3 (24.9) (N = 99)		
	24	30.7 (24.4) (N = 82)	33.1 (24.9) (N = 80)	<0.001	0.01
ODI‡	0	29.0 (9.7) (N = 102)	29.2 (9.7) (N = 102)		
	5	15.0 (12.4) (N = 100)	18.5 (10.6) (N = 102)		
	12	13.9 (11.3) (N = 96)	16.2 (12.0) (N = 100)		
	24	12.0 (11.6) (N = 82)	14.0 (9.9) (N = 80)	<0.001	0.20
HRQOL (15D)§	0	0.86 (0.072) (N = 67)	0.87 (0.068) (N = 74)		
	5	0.89 (0.073) (N = 81)	0.90 (0.069) (N = 83)		
	12	0.90 (0.066) (N = 78)	0.91 (0.073) (N = 81)		
	24	0.91 (0.078) (N = 80)	0.91 (0.082) (N = 76)	0.007	0.98

*All values are means (SD). For all scales and questionnaires, the score increases with severity of pain or symptom, except for the 15D questionnaire, which acts conversely.
† VAS from 0–100.
‡ ODI from 0–100.
§ 15D from 0–1.
¶ *P* values were tested with repeated measures ANOVA. Because of the skewed distribution of the data, logarithmic transformation of all parameters was used, except for the 15D questionnaire, in which the square-root transformation was used. Missing values were substituted with the last value carried forward technique.

Before the 2-year follow-up, 42 of the 204 (20%) dropped out, 6 subjects could not be reached, and 36 did not return the questionnaire for other reasons. Dropouts were divided evenly between the groups (20 in the combination and 22 in the consultation group). Gender distribution, age, duration of pain and baseline pain intensity, disability, and depression were comparable across the entire study sample.

Baseline Characteristics

The combination and consultation groups were comparable in sociodemographic characteristics, including age, gender, level of education, and smoking habits, in duration and localization of LBP, pain intensity, self-rated disability, depression, and HRQOL.[10]

Outcomes

Significant improvement occurred in both groups on every self-rated outcome measurement. Within the 2-year follow-up, significant difference appeared between the groups in pain intensity ($P = 0.01$, ANOVA) but not in self-rated disability ($P = 0.20$, ANOVA) (Table 1). The percentage of daily LBP decreased from 58% to 23% ($P < 0.001$, McNemar symmetry χ^2 test) in the combination and from 62% to 24% ($P < 0.001$) in the consultation group. The proportion of patients using analgesics for their back pain decreased from 32% to 15% and from 36% to 15% in these same 2 groups.

HRQOL increased equally in both groups ($P < 0.001$, ANOVA) (Table 1), without any differences in any of the15D dimensions between the groups. At baseline, the HRQOL of the 2 study groups was significantly worse than that of average 24 to 54-year-old Finns.[11] The subscales of the 15D questionnaire mostly affecting patients with LBP were moving, usual daily activities, pain, affective distress, and sexual life. Despite improvement in these dimensions, scores failed to equal those of the normal healthy population, except for affective distress. HRQOL was not used in the cost-effectiveness analysis because of its high percentage of missing baseline HRQOL data.

The bootstrapping results showed significantly higher incremental effectiveness in VAS, in favor of the combination group (Table 2). At the 2-year follow-up, patients in the combination group were more satisfied with care received during this study than did patients in the consultation group ($P = 0.001$, Pearson χ^2 test).

Annual visits to physicians and the use of physiotherapy or other manual therapies decreased in both groups during the 2-year follow-up. A decrease was more pronounced in the consultation alone group during the sec-

Table 2. Incremental Cost-effectiveness Plane for Pain Intensity (VAS) and Disability (ODI)*

	Incremental Effectiveness (SD) 95% CI	Incremental Costs (SD) 95% CI	ICER (SD) 95% CI
ODI	**1.24** (2.13)	**$1662** (907)	**$−78** (20818)
Original N = 138	1.18−1.30	1637–1687	−655–499
VAS	**4.97** (5.24)	**$1662** (907)	**$512** (15714)
Original N = 138	4.83−5.12	1637–1687	77–949

*Means, standard deviations (SD), and 95% confidence intervals (CI) of the incremental effectiveness, incremental costs, and incremental cost-effectiveness (ICER) were analyzed for pain intensity and disability. Improvement of ODI and VAS was signed positive. ICER = Δ Costs/Δ Effects. Because of this formula, the number of missing values increases by the number of measurement point, especially in cost variables.

Table 3. The Use of Health Care Services and Costs*

	Combination Group (N = 98)		Consultation Group (N = 100)	
	No. of Visits	Costs ($)	No. of Visits	Costs ($)
Totals 12 mos before randomization				
Visits to physicians	3.1 (3.8)	219 (274)	3.0 (2.8)	218 (203)
Visits for physiotherapy or other therapies	9.2 (9.8)	302 (332)	9.6 (9.7)	298 (303)
Other health care costs†		84 (216)		81 (209)
Total health care costs		611 (566)		600 (445)
Costs to the patient‡		163 (237)		223 (428)
Days absent from work	14.1 (27.8)		20.4 (35.1)	
Productivity costs 1 (whole-day salary)		1883 (3700)		2721 (4681)
Productivity costs 2 (half-day salary)		942 (1850)		1361 (2340)
Total costs 1 (whole-day salary)		2550 (3951)		3574 (4944)
		(1620–3480)		(2586–4562)
Total costs 2 (half-day salary)		1646 (2137)		2216 (2634)
		(1214–2077)		(1690–2742)
Annual mean totals during the 24 mos after randomization	N = 81		N = 78	
Visits to physicians	1.8 (2.6)	130 (188)	1.7 (2.1)	122 (151)
Visits for physiotherapy or other therapies	7.2 (8.1)	234 (265)	5.2 (5.3)	162 (169)
Other health care costs†		79 (237)		77 (255)
Total health care costs		448 (493)		362 (449)
Costs to the patient‡		109 (168)		99 (121)
Days absent from work	12.3 (20.5)		14.8 (38.0)	
Productivity costs 1 (whole-day salary)		1632 (2728)		1970 (5068)
Productivity costs 2 (half-day salary)		816 (1364)		985 (2534)
Total costs 1 (whole-day salary)		2262 (3156)		2280 (5294)
		(1561–2963)		(1081–3479)
Total costs 2 (half-day salary)		1427 (1807)		1370 (2842)
		(1025–1829)		(1026–2014)

*All values are means (SD), and 95% CI are reported for total costs. Costs of the 4 manipulation sessions, including traveling costs to the patients, are included in cost analysis. None of the differences between groups in cost variables were significant at the 5% risk level.
† Other health care costs include visits to outpatient clinics, inpatient care in hospitals, and x-ray examinations.
‡ Costs to the patient include use of drugs and traveling as a result of back pain.

ond year, but differences were not significant. Absence from work during the previous year before randomization already differed slightly between groups, but not significantly ($P = 0.07$, Mann-Whitney test). The difference was not explained by employment status. The annual number of sick leave days decreased on average 5 days during the 2-year follow-up in the consultation group, while the decrease was 2 days in the combination group. Variance in productivity costs was large, and, consequently, the difference between groups was not significant. Mean annual total costs decreased $288 in the combination group and $1294 in the consultation group during the 2-year follow-up compared to baseline costs (Table 3). According to bootstrapping, the combination group showed higher incremental costs compared to the consultation group (Table 2). A one-point improvement in the combination group compared to the consultation group in VAS scale cost of $512 (95% confidence interval 77−949) (Table 2). Cost-effectiveness plane and acceptability curve showed that the combination therapy yields acceptable cost-effectiveness in approximately 75% of bootstrapping data if the decision maker's willingness to pay for one-point improvement in VAS is highest $2100. In the same way, according to ODI, if willingness to pay is $4200, 65% of bootstrapping data yield acceptable cost-effectiveness (Figures 1 and 2).

■ Discussion

For patients with cLBP, spinal manipulative therapy with stabilizing exercises and physician information, advice, and encouragement was only slightly more beneficial in reducing pain and leading to patient satisfaction than merely the physician information, advice, and encouragement alone. However, the HRQOL improved equally in both groups. The actual long-term clinical differences were statistically significant but still minor from the clinical point of view. The total annual cost savings were higher in the consultation group. Visits to physicians, physiotherapy, or other manual therapies continued to decrease in both groups from the first follow-up year, as did sick leave days.[10] In the present study, the mere consultation appeared to be more cost-effective than the combination therapy, which was the opposite of the original hypotheses.

The question arises as to whether the outcome measure regarding pain perception in the combination group compared to the consultation group still remains clinically significant at 2-year follow-up. In addition to conventional statistical analysis, the concept of minimal clinically important differences in the outcome scores may be used. It is defined as the smallest difference score that patients perceive as beneficial.[13,14] Regarding VAS, the

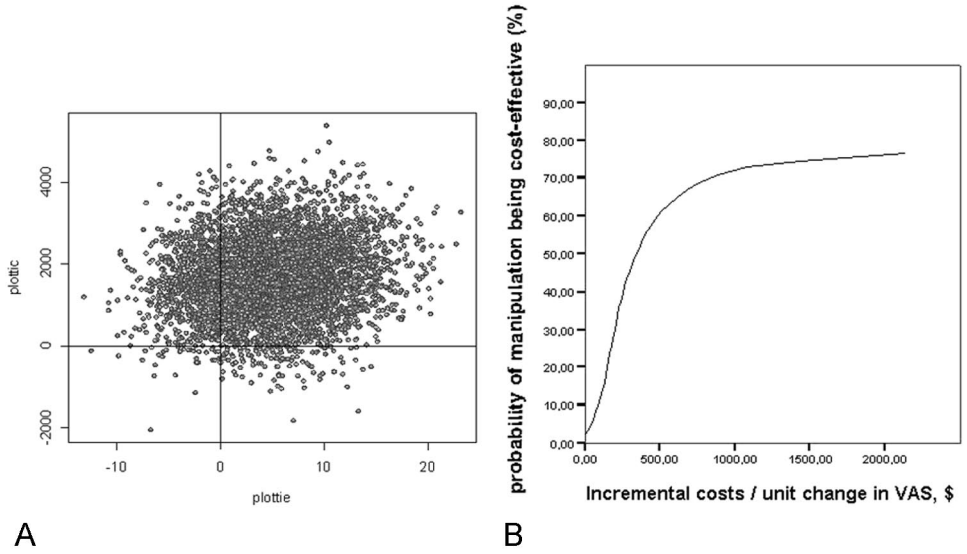

Figure 1. **A**, Incremental cost-effectiveness plane on VAS. Bootstrap result of 5000 replica data. **B**, Cost-effectiveness acceptability curve on VAS. Dotted line shows mean.

minimal clinically important differences value (0–10) has been assessed to be 2, and regarding ODI, the values in different studies from 5.2–16.3.[14–17] Based on this result, the observed statistical difference in the present study at 2-year follow-up (2.4 in the VAS scale of 0–100) is not clinically significant.

In our study, the economic evaluation was carefully conducted, including the analysis of both direct and indirect costs. Incremental cost-effectiveness analysis was made for pain intensity and disability using the bootstrapping techniques. Our intervention was compared to the best available alternative for unspecific patients with LBP at the moment. In a sample of subacute patients, Karjalainen *et al*[18] showed recently that the so-called mini intervention based on individual information was superior to the usual health care. The personal advice and information in the present study was very similar to the regimen of Karjalainen *et al*. The major limitation of our economic evaluation was that the data were collected by a retrospective questionnaire. The recall bias is a well-known problem in economic evaluations. Patients hardly remember health care use beyond 2 months. However, the use of retrospective questionnaires is a common method in cost-effectiveness studies. Burdorf *et al*[19] found questionnaires on sickness absence because of back pain reliable in the 6-month survey. Aalto *et al*[20] showed questionnaires on inpatient days reliable during the previous year. In our study, the baseline data may be an underestimate on health care use and sickness absence. We consider the data from the 24-month study more reliable because the participants were asked to record all health care use and sickness absence as a result of LBP.

According to our knowledge, this is the first study combining manipulative therapy with stabilizing exercises for LBP. For chronic neck pain, Bronfort *et al*[21] found the use of strengthening exercises, either in combination with spinal manipulation or alone, more beneficial than the use of spinal manipulation alone. Previous studies of LBP with at least a one-year follow-up have compared chiropractic manipulation, manipulative therapy, or osteopathic manipulative treatment with physio-

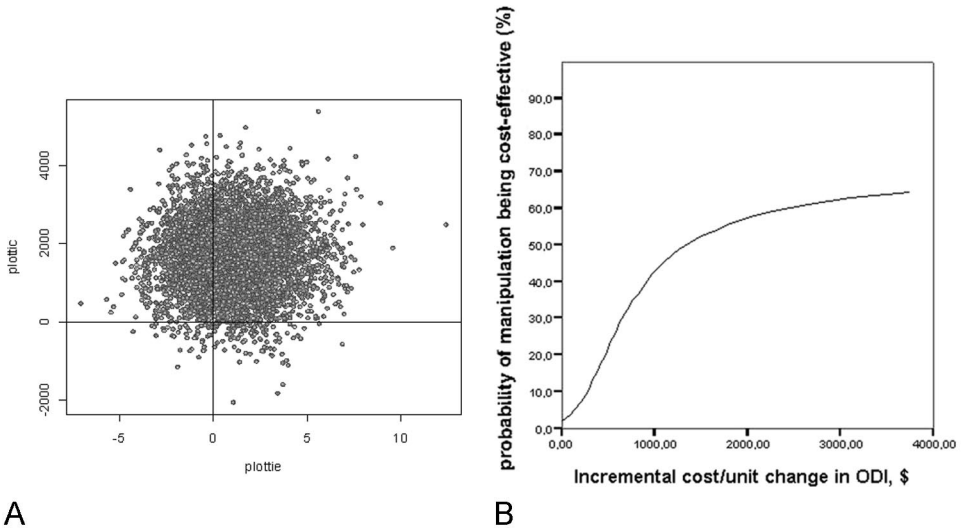

Figure 2. **A**, Incremental cost-effectiveness plane on ODI. Bootstrap result of 5000 replica data. **B**, Cost-effectiveness acceptability curve on ODI. Dotted line shows mean.

therapy,[3,5,7] placebo,[3] treatment by a general practitioner,[3] hospital outpatient treatment,[6] an educational booklet,[5] or chemonucleolysis.[4] No significant differences in clinical effects or costs between chiropractic manipulation and physiotherapy have been found,[5,7] or differences have been minor, in favor of manipulative therapy.[3] These 2 treatments have been only marginally better but more costly than the minimal intervention of an educational booklet[5] and better than placebo or treatment given by a general practitioner.[3] Patients seem to be more satisfied with chiropractic treatment than with hospital outpatient treatment[6] or medical care.[22] Self-care advice and explanation of treatment predicted satisfaction, and reduced the estimated difference between chiropractic and medical patient's satisfaction.[22] Thus far, there are very few RCT of specific stabilizing exercises for the treatment of cLBP. A patient with a radiologic diagnosis of spondylolysis or spondylolisthesis had significant and lasting reduction in pain intensity and functional disability levels compared with that of other commonly prescribed conservative treatment programs.[23]

Comparing our study to other mere manipulative treatment studies, the intergroup and intragroup changes in pain and disability were more pronounced in the present study.[6,7] Our patients were also remarkably satisfied within each of the treatment arms as well.[6] The 4 therapy sessions resulted in lower direct costs than in the study by Skargren *et al*.[7] Hemmila[9] showed that physiotherapy and bone setting had similar effects on quality of life, but both were superior to light exercise. However, none of these interventions could reduce the use of health care services or total costs.[9] It seems obvious that stabilizing exercises, self-care advice, and information added to manipulative treatment gave extra benefit to our patients with cLBP. The combination produced long-lasting effects on subjective pain, disability, quality of life, and satisfaction with care. On the other hand, the positive changes in the consultation group were slower to appear but long lasting as well. The effects on HRQOL were equal, but patients in the consultation group seemed more consistently to change their behavior by reducing their use of health care services and sick leave.

This study raises the question of which elements in the physician consultation were essential for these beneficial changes. Increasing evidence exists that proper patient information, an explanation of the background of the symptoms, findings, and the meaning of the exercises added to encouragement, and an attempt to reduce pain related fear can reduce work absenteeism[24,25] and increase patient satisfaction.[22] It is important that patients consider the care provider as a reliable and knowledgeable expert. Furthermore, the information in the consultation group may have directed patients more consistently and uniformly toward independent self-care and self-efficacy. For the majority of nonspecific patients with LBP, information, advice, and personal communication served adequately as the treatment of choice. Nevertheless, a subgroup of patients who either were dissatisfied or considered the information insufficient would certainly have benefited from the combination treatment with more personal contact with a therapist. Our earlier findings on prognostic factors suggest that psychosocial features may differentiate patients into either good or poor responders.[26] Further investigations have been performed to characterize the psychosocial features for the subgroup of patients with cLBP, who especially benefit from each approach.

■ Conclusion

This study showed that the combined manipulative treatment, exercise, and physician consultation was only slightly more effective for reducing pain but leading clearly to increased patient satisfaction as compared to the physician consultation alone. Physician consultation alone was more cost-effective for both health care use and work absenteeism, and led to equal improvement in disability and HRQOL. It seems obvious that encouraging information and advice are major elements for the treatment of patients with cLBP.

■ Key Points

- Combined manipulative treatment, exercise, and physician consultation were only slightly more effective for reducing pain but leading clearly to increased patient satisfaction as compared to the physician consultation alone at 2-year follow-up.
- Physician consultation alone was more cost-effective for both health care use and work absenteeism, and led to equal improvement in disability and HRQOL.
- For the majority of nonspecific patients with LBP, information, advice, and personal communication served adequately as the treatment of choice.

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