Effectiveness and Cost-Effectiveness of Adding a Cognitive Behavioral Treatment to the Rehabilitation of Chronic Low Back Pain

BERND SCHWEIKERT, ECKART JACOBI, ROBERT SEITZ, REINHARD CZISKE, ANTJE EHLERT, JULIA KNAB, and REINER LEIDL

ABSTRACT. ***Objective.*** To investigate return to work and cost-effectiveness of the addition of cognitive-behavioral treatment to standard therapy compared to standard 3-week inpatient rehabilitation for patients with chronic low back pain.

Methods. A prospective economic evaluation alongside a randomized controlled trial was performed. Outcomes included days off work due to spinal complaints, health-related quality of life, and direct and indirect disease-related costs.

Results. A total of 409 patients with chronic low back pain, who were admitted to a 3-week inpatient rehabilitation, were randomly assigned to usual care or usual care plus cognitive behavioral treatment. Average incremental costs for psychological treatment during rehabilitation were € 127 (95% CI 125.6, 130.9; $p < 0.001$). Six months after rehabilitation, patients in the intervention group were absent from work an average of 5.4 (95% CI –1.4, 12.1; $p = 0.12$) days less than patients receiving usual treatment. Between groups, there were no significant differences in quality-adjusted life-years gained or in direct medical or nonmedical costs. The cognitive behavioral treatment showed lower indirect costs: € 751 (95% CI –145, 1641; $p = 0.097$).

Conclusion. Adding a cognitive behavioral component to standard therapy may reduce work days lost and thus decrease indirect costs. From a societal perspective, the cost of the psychological treatment was compensated by lower indirect costs. (J Rheumatol 2006;33:2519–26)

Key Indexing Terms:
CHRONIC LOW BACK PAIN
COST-EFFECTIVENESS ANALYSIS
HEALTH-RELATED COST
COGNITIVE-BEHAVIORAL THERAPY
HEALTH-RELATED QUALITY OF LIFE
REHABILITATION

From GSF – National Research Center for Environment and Health, Institute of Health Economics and Health Care Management, Neuherberg; Research Institute for Rehabilitation Medicine, University Ulm, Ulm; Rheumaklinik Bad Wurzach, Bad Wurzach; BKK Landesverband Bayern (Association of Company Sickness Funds), Munich; Federseeklinik Bad Buchau, Bad Buchau; and Munich School of Management, Institute of Health Economics and Management, Ludwig-Maximilians-University, Munich, Germany.

Supported by the German Federal Ministry of Education and Research and the Federation of the German Pension Insurance Institutes, grant no. 01GD9820/0.

B. Schweikert, MSc, Health Economist, GSF – National Research Center for Environment and Health, Institute of Health Economics and Health Care Management; E. Jacobi, MD, PhD, Chief Physician, Medical Project Leader, Research Institute for Rehabilitation Medicine, University Ulm; Rheumaklinik Bad Wurzach; R. Seitz, PhD, Health Economist, Project Leader, BKK Landesverband Bayern; R. Cziske, MSc, Psychologist; A. Ehlert, MD, Study Physician, Rheumaklinik Bad Wurzach; J. Knab, MD, Study Physician, Federseeklinik Bad Buchau; R. Leidl, PhD, Head, Health Economics Unit, GSF – National Research Center for Environment and Health, Institute of Health Economics and Health Care Management and Munich School of Management, Institute of Health Economics and Management, Ludwig-Maximilians-University.

Address reprint requests to B. Schweikert, GSF–National Research Center for Environment and Health, Institute of Health Economics and Health Care Management, Ingolstädter Landstrasse 1, D-85764 Neuherberg, Germany. E-mail: bernd.schweikert@gsf.de

Accepted for publication July 20, 2006.

During recent decades, low back pain (LBP) has been recognized as a major health problem in most Western countries[1]. Recent cost-of-illness studies showed that back pain is also a major socioeconomic problem[2-6], with relative cost estimates ranging up to 1.7% of gross national product (GNP) for The Netherlands[7]. For Germany, the annual costs of LBP to the economy have been estimated at € 16 billion (0.8% of GNP), with chronic patients accounting for a third of the total cost[8]. The major cost component is indirect costs caused by lost productive time due to absenteeism and disability. Therefore, return to work is considered a primary goal for treatment[9].

In Germany, people insured in the pension insurance scheme who have chronic LBP are eligible for inpatient rehabilitation in order to prevent the reduction or loss of earning capacity. The standard rehabilitation consists of a treatment combining active physiotherapeutic and balneologic measures. However, previous studies have shown that physical exercise alone has only a limited beneficial effect[10-12].

Cognitive behavioral treatment (CBT), based on the biopsychosocial model of disease, is motivated by the observations that the physiological case fails to sufficiently explain the development of chronic back pain[13] and by strong evi-

dence linking psychological factors to its chronicity[14,15]. Consequently, CBT not only focuses on removing the underlying organic pathology but also tries to reduce disability by modifying pain behavior and cognitive processes. In general, CBT combines elements of operant behavioral training stimulating a positive pain response by distraction, a cognitive component provided by educational elements, and respondent treatment aimed at reducing muscle tension by relaxation techniques[16,17].

Existing controlled randomized studies demonstrate that multidisciplinary treatment is effective in pain and disability and report various results regarding return to work[18-20]. However, little is known about the effectiveness of adding a behavioral program on top of traditional inpatient rehabilitation.

Only a few studies have previously addressed the economic aspects of therapeutic approaches for patients with chronic back pain. Comparing 3 physical exercise methods and usual care, Timm reported "low tech" training therapy to be cost-effective when direct costs were considered[21]. Goossens, *et al* found no economic evidence in favor of adding a cognitive component to an operant treatment[22]. Skouen, *et al* reported an economic advantage of light multidisciplinary treatment for men compared to usual care when "return to work" was translated into indirect costs[20]. Torstensen, *et al* showed cost savings for 2 different exercise treatments compared to self-exercise[23]. Due to methodological heterogeneity in the economic analysis and the cost components, a comparison of results is problematic. The evidence for cost-effective training and behavioral approaches for chronic LBP patients remains relatively weak, especially when compared to the significant burden of this disease.

We examined the effectiveness of the incorporation of CBT into a 3-week inpatient medical rehabilitation program, which traditionally concentrates on physiological treatment. The focus and primary endpoint was "return to work," which is the main goal of the rehabilitation system in the German context.

MATERIALS AND METHODS

About 82% of the German workforce is insured in the public pension system. This pension system provides rehabilitation to insured persons whose earning capacity is threatened due to a chronic condition such as LBP, with the aim of preventing premature retirement. Rehabilitation is provided either after an application and assessment regarding eligibility or on request by the administration. Usually rehabilitation leads to a 3-week inpatient stay in a specialized clinic.

Patients in our study were recruited consecutively after being prescreened by staff of the pension insurance administration, who assessed eligibility for rehabilitation treatment. Final recruitment was performed at admission to the rehabilitation clinic. Patients were included if they had a history of nonspecific LBP of at least 6 months. Medical exclusion criteria were severe comorbidities and an indication of severe spinal pathology such as rheumatoid arthritis, osteoporosis, fibromyalgia, oncologic diseases, or radiologically-proven intervertebral disc rupture. Further, patients were excluded if they had already filed an application for early retirement or if they were unemployed for more than 12 months. Prior to trial inclusion, patients were informed by the clinic physician and provided informed consent. Within the first day of inpatient stay, patients were randomly assigned to one of 2 groups: usual care or usual care plus CBT.

The randomization was performed by an external biometrical unit using Rancode Professional 3.6 and was stratified by age and a variable (3 categories), "number of back pain related sick days in the 12 months prior to the rehabilitation." Blinding of patients, clinic physicians, and the psychologists administering the treatment was not possible due to the nature of the intervention.

In the usual care group, patients received a standardized conventional 3-week inpatient rehabilitation program consisting of daily physiotherapy in small groups, massage of spinal region, electrotherapeutical measures, 1-hour seminar regarding back training, twice-daily exercise program, seminars on lifestyle, and risk factors for back pain and its process of becoming chronic. Patients in the intervention group were additionally treated by a cognitive-behavioral pain management program[24,25] comprising 6 group sessions of 1.5 hour each plus one individual preparatory session (0.5 hour) and a final individual session (0.5 hour). The individual preparatory session prior to the group sessions was designed to investigate former attempts and present strategies of coping with back pain and to enhance motivation for participating in the psychological training. The individual session at the end of the program served to encourage patients to utilize what they were taught in everyday life. The study was performed in 2 German rehabilitation centers. In each clinic, one trained psychologist specializing in pain was in charge of the program and the training was conducted by this person only. The cognitive-behavioral program is essentially the one described by Frettlöh, *et al*[25], which has been shown to be effective regarding pain intensity, control over pain, and catastrophizing, with results being maintained at followup after 6 months[17].

The program had 2 main goals: teaching patients methods like relaxation, distraction of attention, and cognitive reappraisal of pain and stress to reduce their pain; and teaching patients to detect negative attitudes and thoughts about their pain and replacing them with more favorable coping strategies.

The 6 group sessions, with an average group size of 6 patients (maximum 8), had the following topics: (1) onset and development of chronic LBP: physical and psychological factors in back pain; (2) role of attention in pain and means of focusing on distracting thoughts and actions; (3) stress and pain: methods of stress reduction such as cognitive reappraisal of stress stimuli; (4) social stress and pain: methods of gaining self-confidence; (5) mood and pain: ways of adopting a more positive attitude; and (6) thoughts and pain: fighting negative thoughts and attitudes such as catastrophizing.

Each session was divided into 3 parts: a theoretical introduction to the topic, followed by a group discussion about personal experiences concerning the topic of the day, and finally exercises in pain management techniques like progressive muscle relaxation (PMR) or cognitive reappraisal of pain and stress. All patients received an audiotape with the PMR training, which they were asked to use daily. Compliance was controlled by asking participants at the beginning of each session whether there had been any problems exercising. Among the variables assumed to be influenced by treatment, the most important were functional capacity of the back, depression, anxiety, and back pain. Main sociomedical outcomes were number of days off work in the followup period of 6 months following the discharge from rehabilitation. Data on sick leave were derived from sickness insurance funds. Health-related quality of life (HRQOL) was measured by the EuroQol questionnaire, the psychometric properties of which were successfully tested in a pilot study in a similar population of patients with LBP[26] and which has been previously recommended for these patients[27,28]. Quality-adjusted life-years (QALY) were the main health outcome in economic evaluation, in accord with current guidelines[28,29]. Primary evaluation was performed using the patients' preferences derived using a visual analog scale (VAS). To provide a broad basis of comparison, we also used a recently described European population-based valuation formula[30]. Patients completed EuroQol questionnaires at admission, at discharge, and 6 months after discharge (the questionnaire was sent by mail).

For the economic analysis, costs were measured from a societal perspective. Data for complete inpatient resource utilization, including medical and nonmedical costs, were collected on an individual basis using routine documentation in the usual care and experimental groups. Resource utilization was valued with prices derived from the clinic accounting systems. Postrehabilitation healthcare utilization, nonmedical direct costs for the

patient, and indirect costs associated with production losses due to LBP were measured by patient administered cost diaries[31]. In addition, the number of days off work was available from sickness insurance records. Most subjects filled in cost diaries in the first and sixth month after rehabilitation. About 20% (n = 76) of the sample was randomly assigned to complete 6 cost diaries covering the total followup period. A complete set of 6 cost diaries was received from 41 subjects, whose baseline characteristics were not significantly different from those of the overall sample. Since monthly costs measured by continuous cost measurements and costs based on extrapolation of months 1 and 6 of the 41 subjects showed similar results, we concluded that linear extrapolation validly approximates the total costs in the observation period. Accordingly, costs of patients, for whom only 2 diaries covering first and sixth month were available, were linearly extrapolated over the 6-month period. In line with recent guidelines direct costs were valued using average market prices when available and administrative charges otherwise[41]. Indirect costs were valued by age- and sex-adjusted average labor costs incorporating salaries and social insurance premiums paid by employers and employees. All costs are expressed in 2001 Euros. The mean exchange rate in 2001 was € 0.8952 per US dollar.

In economic evaluation of health technologies, incremental effects and incremental costs are combined in a single outcome measure: the incremental cost-effectiveness ratio (ICER), defined as the ratio of the mean difference in cost (C) and mean difference in effects (E): ICER = $\Delta C/\Delta E$.

The effect of alternative valuation approaches for important cost components was assessed using sensitivity analyses.

Statistical analysis. For univariate testing of significance of cost and HRQOL, Student's t test was used. Secondary variables relating to the patient outcome of the study, such as pain and physical functioning, were tested using Wilcoxon's matched-pairs signed-ranks test. For analysis of ICER, the nonparametric bootstrap procedure was applied using an angular transformation procedure that is recommended if effect-difference is small[32,33]. Bootstrapping is a technique that can simulate a distribution of the ICER estimates by repeatedly sampling the observed sample without replacement.

To control for missing values and attrition in HRQOL data due to nonresponse in the followup, a multiple imputation procedure was used[34,35]. This method is increasingly used in applied research, and has been proven to be a valuable alternative compared to imputation procedures like mean imputation or other ad hoc imputation procedures or missing data techniques[36]. Calculation and statistical analysis was performed using the SAS software package (SAS Software 2003).

Ethical issues. The study was approved by the ethics commission of the medical association of the State of Baden-Wuerttemberg. Patients received written information about the study and interventions, according to the Declaration of Helsinki, before being asked to give informed consent.

RESULTS

Four hundred nine patients were enrolled in the trial and 382 (93%) completed the trial by time of discharge from the rehabilitation. All received the treatment as intended (Figure 1). The 27 withdrawals were predominantly from the treatment group (21 vs 6). While most of the dropouts in the control group left the study for medical reasons (n = 4), the majority (n = 13) in the treatment group withdrew due to motivational problems. While the treatment groups were similar at baseline in terms of patient characteristics (Table 1), they differed regarding dropouts. In contrast to the control group, patients leaving the trial from the treatment group were on average younger, showed higher EuroQol scores, and were predominantly male. Information on days off work was obtained from the sickness insurance fund database for 343 (84%) patients, and 264 patients (65%) provided followup information after 6 months regarding costs and HRQOL.

During the 6-month followup period after rehabilitation, patients in the cognitive behavioral treatment group were absent from work on average 11.4 days, 5.4 (95% CI –1.4, 12.1; p = 0.12) days less than patients receiving usual treatment (Table 2). None of the behavioral measures used resulted in significant differences between the control and intervention groups during the inpatient rehabilitation.

The HRQOL scores improved similarly in both groups during the inpatient rehabilitation. After 6 months, HRQOL in both groups was lower compared to discharge values, with the decline being less pronounced in the intervention group. While HRQOL in complete cases was significantly different, it became insignificant when accounting for missing data by multiple imputation techniques (Table 2). Transforming HRQOL in QALY and accounting for baseline differences, no significant difference between groups could be detected (Δ = 0.008; 95% CI 0.028, –0.0113; p = 0.396). As with HRQOL, scores of the secondary endpoint variables (functional capacity, pain intensity, depression, anxiety) improved during rehabilitation, but no significant differences between groups could be detected (Table 2). With the exception of functional capacity, rates of improvement in the CBT group tended to be higher.

Cost analysis. As expected, the cost of psychological treatment was the only cost component showing a significant cost difference between the study arms during inpatient rehabilitation (Table 3). For the overall sample, the difference in psychological treatment was € 127 (95% CI 125.6, 130.9; p < 0.001), which was partly offset by higher costs of the control group due to a slightly higher average duration of stay, because a higher proportion of patients obtained a treatment extension. Adding up all components, no significant differences in direct medical or direct nonmedical costs were found during the 6-month followup (Table 3). According to sickness insurance fund data, indirect costs due to sick leave during followup were lower in the experimental group (€ 1441) than in the control group (€ 2192). Thus, based on the more complete administrative data on days off due to LBP, the difference in indirect costs amounted to € 751 (95% CI –145, 1641; p = 0.097). Adding up costs for patients with complete information, the difference in total costs between groups was found to be of borderline significance (p = 0.054).

Cost-effectiveness analysis. After 6 months, there was no significant difference in the health outcomes measured by QALY gained. Due to the lower indirect costs, the intervention would be cost-saving from a societal perspective, with the resulting ICER amounting to € –126,731/QALY. Bootstrapping techniques applied to account simultaneously for the uncertainty in incremental cost and incremental effects showed that 61% of the repetitions lay in the southeast quadrant, indicating dominance of the treatment (Figure 2).

The sensitivity of the total cost difference with regard to alternative valuation approaches is shown in Figure 3. As expected, using the friction cost approach instead of the human capital approach has the greatest effect on cost estimates,

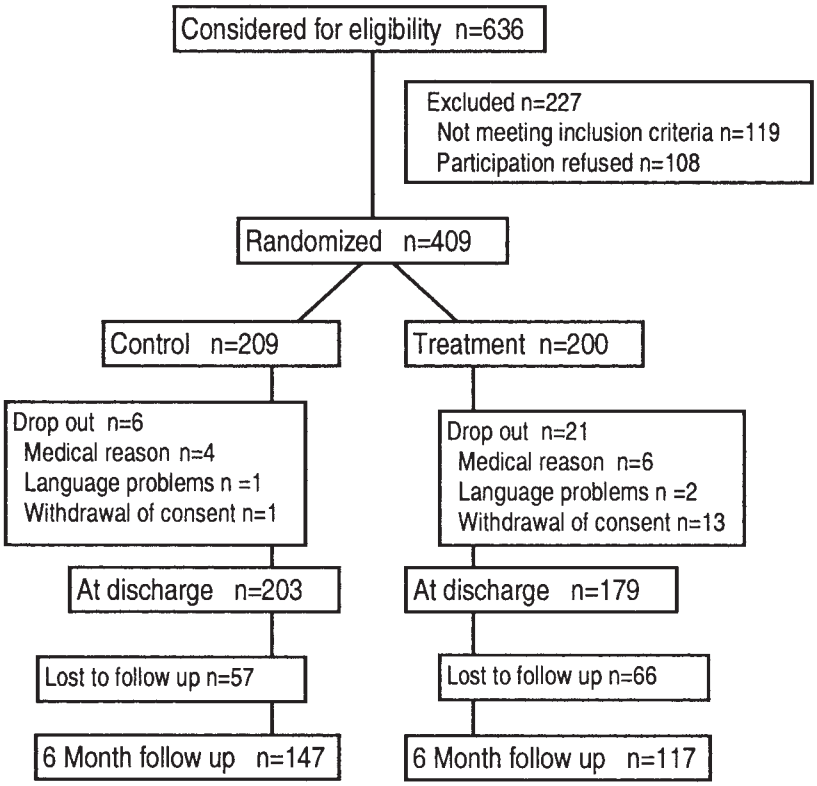

Figure 1. Progress of participation through the trial. Due to different combinations of quality of life questionnaires not being completed, numbers for analysis differ. Cost analysis can be performed on 259 subjects (146 control, 113 CBT) quality of life analysis on 238 patients (133 control, 105 CBT).

Table 1. Baseline characteristics of participants.

	Control		Cognitive Behavioral Treatment		Total	
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD
Age (mean ± SD)	209	46.6 ± 9.1	200	46.9 ± 8.5	409	46.7 ± 9.1
Pain intensity*	209	4.5 ± 1.2	194	4.3 ± 1.3	403	4.4 ± 1.3
Functional capacity**	202	72.2 ± 18.3	184	76.0 ± 19.2	386	74.0 ± 18.8
Depression†	196	7.4 ± 6.3	168	8.3 ± 7.3	364	7.8 ± 6.8
Anxiety††	196	38.8 ± 9.9	167	39.2 ± 10.4	363	39.0 ± 10.1
BMI	209	27.2 ± 3.5	194	27.2 ± 4.2	403	27.2 ± 3.8
Male (%)	173 (82.8)		166 (83.0)		339 (82.9)	
Female (%)	36 (17.2)		34 (17.0)		70 (17.1)	
Sick listed due to low back pain in last year (%)						
No. (%)	52 (24.9)		51 (25.5)		103 (25.2)	
< 6 mo	146 (69.9)		137 (68.5)		283 (69.2)	
> 6 mo	11 (5.3)		12 (6.0)		23 (5.6)	

* Subjective intensity of back pain, rated according to German school grades from 1 (pain-free) to 6 (very strong pain). ** Hannover functional questionnaire (FFbH), range 0 (no limitations) to 100 (severe limitations). † Depression scale, range 0 (not depressed) to 48 (strongly depressed). †† State-Trait Anxiety Inventory, range: 20 (no problems) to 80 (severe problems). BMI: body mass index.

reducing the estimated cost difference by over € 700. However, since variance is also reduced considerably, p values remain almost stable (p = 0.08). Based on the sample with complete costs and outcome information, the bootstrap distribution and the shares of replicates falling in any quadrant remain largely unaffected by sensitivity analyses (data not shown).

DISCUSSION

Although it was applied by experienced pain psychologists, there was no detectable effect of CBT added to standard therapy for LBP. Neither pain nor emotional discomfort could be reduced by the program. This is a surprising result, as cognitive-behavioral measures have been shown

Table 2. Results in work absence, quality of life, and quality-adjusted life-years (QALY) after rehabilitation.

	Control			Cognitive Behavioral Treatment				
	n	Mean	SD	n	Mean	SD	Difference	p*
Days off work due to spinal complaints	182	16.8	34.1	161	11.4	28.9	–5.4	0.115
Indirect cost in €		2192.1	4622.9		1441.1	3713.4	–751.0	0.097
Quality of life								
EuroQol on admission	184	59.3	16.6	158	60.8	17.6	1.5	0.422
EuroQol at discharge		68.6	19.5		70.3	19.3	1.7	0.408
Δ admission–discharge		9.3	15.2		9.6	18.3	0.3	0.892
EuroQol 6 mo followup	133	63.8	19.9	105	70.0	17.7	6.2	0.011
Δ 6 mo followup–discharge		–4.5	14.9		–2.4	17.8	2.1	0.327
QALY (VAS)[§]		0.373	0.080		0.381	0.073	0.008	0.396
QALY (Index)***	130	0.399	0.056	102	0.401	0.053	0.002	0.870
Sensitivity analysis; imputed data[†]								
EuroQol on admission	203	58.5	16.7	179	60.0	17.8	1.5	0.410
EuroQol at discharge		67.7	19.5		69.3	19.6	1.6	0.423
EuroQol 6 mo followup		62.9	19.8		66.8	18.8	3.8	0.103
QALY (VAS)[‡]		0.371	0.100		0.378	0.094	0.007	0.523
QALY (Index)***		0.394	0.070		0.396	0.065	0.002	0.783
Changes in secondary variables, Δ admission – discharge								
Functional capacity**	194	3.5	13.4	169	2.8	12.3	–0.7	0.830
Depression[§§]	191	–1.6	4.2	168	–2.3	4.7	–0.7	0.340
Anxiety[††]	192	–2.3	6.3	165	–2.7	6.9	–0.4	0.301
Subjective back pain[‡‡]	193	–1.2	1.2	170	–1.2	1.2	0.0	0.930

* Unpaired t test. [§] QALY calculated based on transformed VAS. [†] Multiple imputation procedure using Markov chain Monte Carlo technique for imputation. [‡] Adjusted for differences in baseline level of HRQOL. ** Hannover functional questionnaire (FFbH), range 0 (no limitations) to 100 (severe limitations). [§§] Depression scale, range 0 (not depressed) to 48 (strongly depressed). [††] State-Trait Anxiety Inventory, range: 20 (no problems) to 80 (severe problems). [‡‡] Subjective intensity of back pain, rated according to German school grades from 1 (pain-free) to 6 (very strong pain). *** Based on median-adjusted European EQ-5D formula[30].

Table 3. Cost of inpatient treatment and low back related cost in followup period.

	Control		Cognitive Behavioral Treatment			
	Mean	SD	Mean	SD	Δ	p
Direct medical inpatient costs*	2035.0	325.0	2157.1	344.1	122.1	< 0.001
Psychological treatment	1.4	10.7	128.3	17.9	126.8	< 0.001
Physician services	164.6	31.4	163.5	29.9	–1.1	0.745
Nursing	197.2	26.5	196.7	25.6	–0.5	0.845
Therapeutics	497.2	104.0	491.8	107.5	–5.4	0.620
Medication and diagnostics	36.8	24.3	40.7	27.3	3.9	0.147
Accommodation	1137.9	325.6	1136.2	332.9	–1.7	0.961
Direct medical outpatient costs[§]	350.9	481.1	337.5	524.1	–13.4	0.830
Physician	160.0	207.9	112.5	175.2	–47.5	0.057
Physiotherapy	117.3	242.8	115.8	217.0	–1.5	0.959
Other therapy	30.3	140.0	39.0	189.9	8.7	0.684
Drugs	70.5	154.2	110.1	301.5	39.6	0.204
Direct nonmedical cost	651.2	779.0	662.2	762.3	11.0	0.909
Travel	147.9	242.8	130.8	206.8	–17.1	0.549
Activities	239.9	361.3	194.4	264.4	–45.5	0.242
Aids and other expenses	263.4	454.8	337.1	573.5	73.7	0.264
Indirect costs	7447.4	7673.5	5687.8	5342.0	–1759.4	0.034
Indirect costs during rehabilitation	3761.1	801.9	3747.6	735.0	–13.5	0.865
Indirect cost during 6 mo followup	3563.61	7556.65	1868.5	5291.7	–1695.1	0.035
Physician visit	60.2	259.5	61.8	262.6	1.6	0.962
Total cost	10,519.9	8073.6	8849.3	5820.0	–1670.6	0.054

* Data for inpatient costs are based on routine data and study documentation for n = 201 in control group and n = 177 in treatment group. [§] Data for outpatient costs are based on patient-reported data, n = 146 in control group and n = 113 in treatment group.

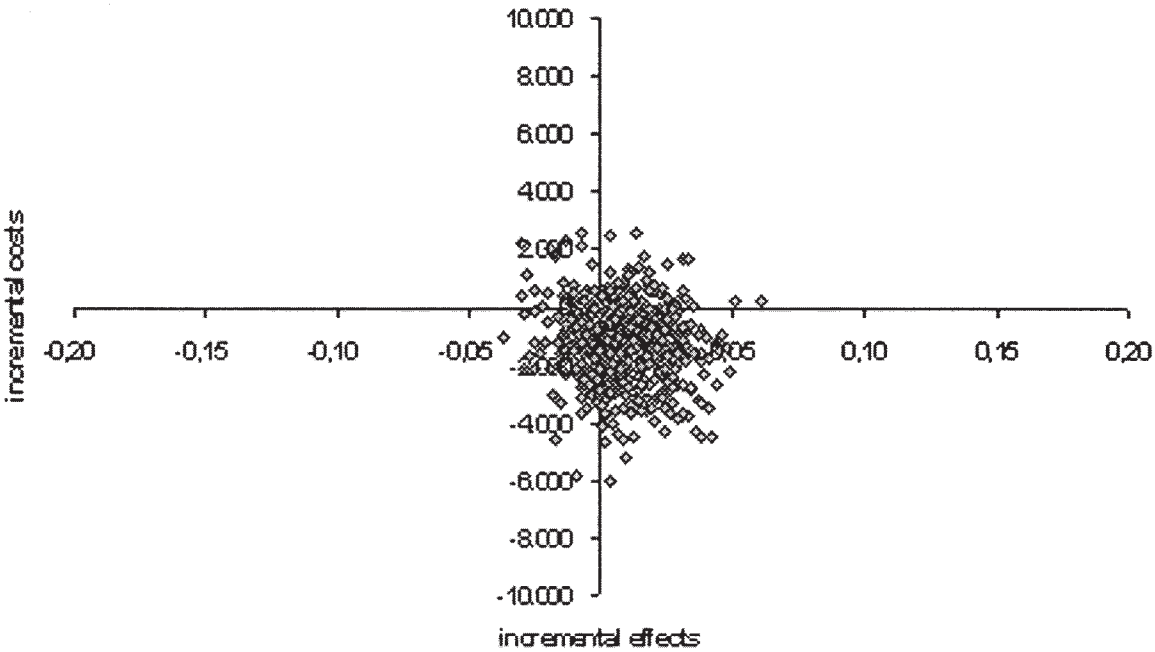

Figure 2. Bootstrapping analysis in the cost-effectiveness plane (1000 bootstrap replications); incremental cost in €, incremental effects expressed in QALY gained (by VAS). The origin of this plane presents the reference strategy (control group). Points in the northwest quadrant (higher cost, lower benefits) are dominated by the reference strategy, whereas the southeast quadrant indicates superiority (lower cost, higher benefits) of the experimental strategy. Points in the remaining 2 quadrants indicate tradeoff situations, since higher benefits coincide with higher cost or lower ones with cost savings.

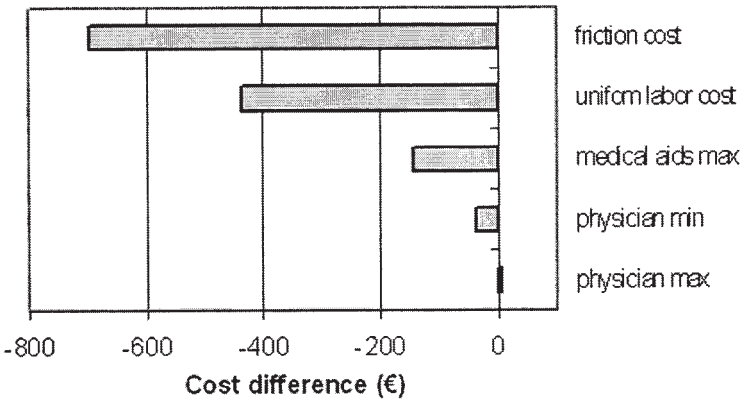

Figure 3. Sensitivity analysis for cost differences. Deviations from the base analysis of total cost difference (control group minus intervention group = € 1670). The friction cost method assumes that in the presence of unemployment, productivity losses due to a longterm absent employee will be incurred just as long as it takes to replace the employee and restore the firm's work capacity (friction period). We took 71 days as the friction period in this context[41]. In "uniform labor costs," age- and sex-specific labor costs were replaced by overall mean labor costs. On the direct costs side, the effects of using a maximum and minimum rate for physician visits ("physician min," "physician max") and alternative valuation for specific aids ("medical aids max") were analyzed.

to have beneficial effects on pain and psychosocial functioning[37].

Moreover, Basler, *et al*[17] achieved pertinent improvements, lasting at least 6 months. One explanation for the different results might be that in Basler's study, the patients received many more training units (12 weekly sessions of 2.5 h). Thus, the 6 sessions in our study may have been insufficient to produce a significant effect compared to standard therapy. Increasing the number and length of the sessions would raise the immediate costs, but given the relatively low contribution

to total costs, an increase in training intensity could be considered in future implementations. However, it hardly seems possible to carry out more than 6 sessions in addition to standard therapy within the fixed stay period of 21 days.

The drop in HRQOL after discharge was less pronounced in the intervention group, consistent with findings reporting a positive maintenance of treatment effects by CBT compared to usual care[38]. However, no significant incremental effect could be detected. Transforming HRQOL into QALY, no statistically significant difference was found. There was also no qualitative difference in QALY using either patient or population based preferences for the valuation of health states.

Despite the results showing no difference in clinical variables and HRQOL, the study led to a reduction in days off work due to spinal complaints after 6 months, which also led to a reduction in indirect costs. The sex distribution was heavily dominated by men, which might raise doubts about the generalizability of the results. However, according to pension insurance statistics, 71% of the patients receiving rehabilitation treatment were male, and generalization of results for this group seems justified. Further, no significant influence of sex on health outcomes or costs could be detected by regression analysis.

Could effectiveness be enhanced and number or length of sessions reduced by focusing on the most effective elements of the program? To assess this, the relative contribution of each element of the program must be known.

Similar to other pain management programs, ours is intended to be comprehensive and thus contains numerous elements to help patients cope with pain. Unfortunately, the effectiveness of the individual elements cannot be assessed unless a tedious dismantling process is undertaken. The meta-analysis of chronic LBP by Ostelo, *et al* shows that PMR, a main component of our program, has at least a short-term effect on pain and behavioral outcomes (pain behavior), compared to waiting-list controls[37]. The effects of PMR and cognitive methods combined are also pertinent; but individually, neither method is significantly superior to the other. Behavioral strategies leading to a reduction in catastrophizing thoughts may also may be effective[39].

Focusing on PMR may allow the number of sessions or the length of each session to be reduced, but compared to other CBT programs that have been shown to be effective, 6 sessions are not very many[17].

A relevant limitation of our study is the problem of incomplete data due to missing values in the self-administered quality of life questionnaire and due to the attrition at followup. The method of multiple imputation was used to account for potential distortion due to missing information and to test the robustness of results based on complete case analysis. It gives a more conservative estimate of the difference in HRQOL after 6 months, with results only slightly in favor of the intervention on the basis of the complete case analysis.

The appropriateness of the imputation procedure also depends on assumptions about the attrition process that cannot be tested statistically. On the cost side, the incompleteness of patient reported data was accounted for by using administrative data for the dominant cost component of indirect costs, which were available for 84% of the sample.

Comparisons of indirect costs and days of sick leave of the more complete data set obtained with multiple imputation techniques suggest that the results in complete cases are slightly biased in favor of the experimental treatment. However, negative results with respect to the intervention seem highly unlikely.

It may also be noted that the main socioeconomic outcome of sick leave days due to spinal complaints was not affected severely by missing data, since administrative data were used. The result on this variable still points toward a relevant difference between groups in sick leave and indirect costs.

The empirically measured average cost of the psychological intervention during inpatient rehabilitation was € 127, with potential savings in indirect costs amounting to € 751 based on the more complete sickness insurance fund data. In Germany, costs for inpatient rehabilitation are covered by pension insurance, while the employer and the sickness insurance funds benefit from a reduction in sick leave. Since the responsibility is split, the financial incentives for implementing such an additional treatment are rather low if this treatment does not lead to longterm savings in payments by the pension funds. However, the pension funds are legally obliged to improve work capacity even if they do not benefit financially. As the bootstrap analysis demonstrates, even if cost savings are more likely than in any other scenario there remains considerable uncertainty about the health economic consequences.

In contrast to the study of Goossens, *et al,* which in design and intervention comes closest to our study, the observed reduction in indirect costs in the intervention group compensated for the direct costs of the intervention[22]. However, the results of this study are similar to those of Skouen, *et al*, who found a reduction in indirect costs in the male subsample[20]. In both studies, the indirect costs were the dominant cost component. Accordingly, economically advantageous therapies must aim to reduce absenteeism and related indirect costs. The goal of the program was to improve pain behavior and to interrupt the process of pain sensitization and increasing pain perception. However, the mechanisms by which the intervention leads to a reduction in work days lost require further investigation.

In conclusion, adding a cognitive behavioral intervention to the standard treatment of inpatient rehabilitation did not improve the HRQOL of the patients with chronic back pain significantly. Patients in the intervention group tended to have fewer days off work and lower indirect costs than members of the control (usual care) group. In terms of cost-effectiveness, significant uncertainties remain.

From a societal perspective, implementing the program in routine medical care may well be considered as it tends to reduce the days off work, as shown in this study, and thus

would reduce productivity costs, which is an important goal of rehabilitation. Further research should investigate the "active ingredients" of the program, e.g., by systematically varying parts of the treatment.

REFERENCES

1. Andersson G. Epidemiological features of chronic low-back pain. Lancet 1999;354:581-5.
2. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103.
3. Straaton KV, Maisiak R, Wrigley JM, Fine PR. Musculoskeletal disability, employment, and rehabilitation. J Rheumatol 1995;22:505-13.
4. Rizzo J, Abbott T, Berger M. The labor productivity effects of chronic backache in the United States. Med Care 1998;36:1471-88.
5. Linton SJ, Ryberg M. Do epidemiological results replicate? The prevalence and health-economic consequences of neck and back pain in the general population. Eur J Pain 2000;4:347-54.
6. Maetzel A, Li L. The economic burden of low back pain: a review of studies published between 1996 and 2001. Best Pract Res Clin Rheumatol 2002;16:23-30.
7. van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. Pain 1995;62:233-40.
8. Bolten W, Kempel-Waibel A, Pforringer W. Analysis of the cost of illness in backache [German]. Med Klin 1998;93:388-93.
9. Hoffman RM, Turner JA, Cherkin DC, Deyo RA, Herron LD. Therapeutic trials for low back pain. Spine 1994;19:2068S-2075S.
10. van Tulder MW, Malmivaara A, Esmail R, Koes BW. Exercise therapy for low back pain. Cochrane Database Syst Rev 2000:CD000335.
11. van Tulder MW, Ostelo RW, Vlaeyen JW, Linton SJ, Morley SJ, Assendelft WJ. Behavioural treatment for chronic low back pain. Cochrane Database Syst Rev 2000:CD002014.
12. Mannion AF, Muntener M, Taimela S, Dvorak J. Comparison of three active therapies for chronic low back pain: results of a randomized clinical trial with one-year follow-up. Rheumatology Oxford 2001;40:772-8.
13. Waddell G. A new clinical model for the treatment of low-back pain. Spine 1987;12:632-44.
14. Linton SJ. A review of psychological risk factors in back and neck pain. Spine 2000;25:1148-56.
15. Deyo RA, Diehl AK. Psychosocial predictors of diasbility in patients with low back pain. J Rheumatol 1988;15:1557-64.
16. Turk DC, Flor H. Etiological theories and treatments for chronic back pain. II. Psychological models and interventions. Pain 1984;19:209-33.
17. Basler HD, Jakle C, Kroener-Herwig B. Incorporation of cognitive-behavioral treatment into the medical care of chronic low back patients: a controlled randomized study in German pain treatment centers. Patient Educ Couns 1997;31:113-24.
18. Alaranta H, Rytokoski U, Rissanen A, et al. Intensive physical and psychosocial training program for patients with chronic low back pain. A controlled clinical trial. Spine 1994;19:1339-49.
19. Indahl A, Haldorsen EH, Holm S, Reikeras O, Ursin H. Five-year follow-up study of a controlled clinical trial using light mobilization and an informative approach to low back pain. Spine 1998;23:2625-30.
20. Skouen JS, Grasdal AL, Haldorsen EM, Ursin H. Relative cost-effectiveness of extensive and light multidisciplinary treatment programs versus treatment as usual for patients with chronic low back pain on long-term sick leave: randomized controlled study. Spine 2002;27:901-10.
21. Timm KE. A randomized-control study of active and passive treatments for chronic low back pain following L5 laminectomy. J Orthop Sports Phys Ther 1994;20:276-86.
22. Goossens ME, Rutten-Van Molken MP, Kole-Snijders AM, Vlaeyen JW, Van Breukelen G, Leidl R. Health economic assessment of behavioural rehabilitation in chronic low back pain: a randomised clinical trial. Health Econ 1998;7:39-51.
23. Torstensen T, Ljunggren A, Meen H, Odland E, Mowinckel P, Meijerstam S. Efficiency and costs of medical exercise therapy, conventional physiotherapy, and self-exercise in patients with chronic low back pain. A pragmatic, randomized, single-blinded, controlled trial with 1-year follow-up. Spine 1998;23:2616-24.
24. Basler HD. Group treatment for pain and discomfort. Patient Educ Couns 1993;20:167-75.
25. Frettloh J, Franz C, Jäkle C, et al. Das Manual. In: Basler H, Kroener-Herwig B, editors. Psychologische Therapie bei Kopf-und Rückenschmerzen ein Schmerzbewältigungsprogramm zur Gruppen-und Einzeltherapie. München: Quintessenz; 1995:51-186.
26. Seitz R, Leidl R, Jacobi E. Psychometric properties of the "EuroQol" among inpatient rehabilitation patients with diseases of the musculoskeletal system [German]. Zeitschrift für Gesundheitswissenschaften 1999;7:210-32.
27. Deyo RA, Battie M, Beurskens AJ, et al. Outcome measures for low back pain research. A proposal for standardized use. Spine 1998;23:2003-13.
28. Drummond MF, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes. Oxford: Oxford University Press; 1995.
29. Hannoveraner Konsensgruppe. German recommendations for health care economic evaluation studies. Revised version of the Hannover consensus. Hannover Consensus Group [German]. Med Klin 2000;95:52-5.
30. Greiner W, Weijnen T, Nieuwenhuizen M, et al. A single European currency for EQ-5D health states: Results from a six-country study. Eur J Health Econ 2003;4:222-31.
31. Becker A, Seitz R, Jacobi E, Leidl R. Cost evaluation by a patient questionnaire: pilot study of a weekly cost diary [German]. Rehabilitation (Stuttg) 2001;40:12-20.
32. Briggs AH, Wonderling DE, Mooney CZ. Pulling cost-effectiveness analysis up by its bootstraps: a non-parametric approach to confidence interval estimation. Health Econ 1997;6:327-40.
33. Cook JR, Heyse JF. Use of an angular transformation for ratio estimation in cost-effectiveness analysis. Stat Med 2000; 19:2989-3003.
34. Landrum MB, Becker MP. A multiple imputation strategy for incomplete longitudinal data. Stat Med 2001;20:2741-60.
35. Schafer JL. Multiple imputation: a primer. Stat Methods Med Res 1999;8:3-15.
36. Oostenbrink JB, Al MJ, Rutten-van Molken MP. Methods to analyse cost data of patients who withdraw in a clinical trial setting. Pharmacoeconomics 2003;21:1103-12.
37. Ostelo RW, van Tulder MW, Vlaeyen JW, Linton SJ, Morley SJ, Assendelft WJ. Behavioural treatment for chronic low-back pain. Cochrane Database Syst Rev 2005:CD002014.
38. Keel PJ, Wittig R, Deutschmann R, et al. Effectiveness of in-patient rehabilitation for sub-chronic and chronic low back pain by an integrative group treatment program (Swiss Multicentre Study). Scand J Rehabil Med 1998;30:211-9.
39. Spinhoven P, Ter Kuile M, Kole-Snijders AM, Hutten Mansfeld M, Den Ouden DJ, Vlaeyen JW. Catastrophizing and internal pain control as mediators of outcome in the multidisciplinary treatment of chronic low back pain. Eur J Pain 2004;8:211-9.
40. Goossens M, Rutten Van Molken M, Kole Snijders A, Vlaeyen J, Van Breukelen G, Leidl R. Health economic assessment of behavioural rehabilitation in chronic low back pain: a randomised clinical trial. Health Econ 1998;7:39-51.
41. Krauth C, Hessel F, Hansmeier T, Wasem J, Seitz R, Schweikert B. Empirical standard costs for health economic evaluation in Germany — a proposal by the working group methods in health economic evaluation [German]. Gesundheitswesen 2005;67:736-46.