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Published in:
SPINE

DOI:
10.1097/BRS.0000000000003550

SPINE An International Journal for the study of the spine, Publish Ahead of Print

DOI: 10.1097/BRS.0000000000003550

Can we change health care costs in patients with complex backs pain? Results from a 5 year before and after study

Remko Soer, PhD[1,2], Michiel F. Reneman, PhD[3], Jochen O. Mierau, PhD[4], Henrica R. Schiphorst Preuper, MD, PhD[1,3], Patrick Stegeman, MPA[1], Bert L.G.N. Speijer, MPA[1], Hermien H. Dijk, MSc[4], Nynke Buwalda, MSc[4], André P. Wolff, MD, PhD[1,5], Maarten H. Coppes, MD, PhD[1,6]

1. University of Groningen, University Medical Center Groningen, Groningen Spine Center, Groningen, The Netherlands.
2. Saxion University of Applied Sciences, Expertise Center of Health and Movement, Enschede, The Netherlands.
3. University of Groningen, University Medical Center Groningen, Department of Rehabilitation Medicine, Groningen, The Netherlands.
4. University of Groningen, Faculty of Economics and Business, Groningen, The Netherlands.
5. University of Groningen, University Medical Center Groningen, Anaesthesiology Pain Center, Groningen, The Netherlands.
6. University of Groningen, University Medical Center Groningen, Department of Neurosurgery, Groningen, The Netherlands.

Corresponding Author: R. Soer PhD., Groningen Spine Center, P.O. Box 30.001, 9750 RB Groningen, The Netherlands, Tel: 0031612750780; Email: r.soer@umcg.nl

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work.

No relevant financial activities outside the submitted work.

Abstract

Study Design

A before and after study cohort study

Objective

To examine changes in health care costs after multidisciplinary spine care in patients with complex Chronic Back Pain (CBP); to analyze the predictive value of patient and disease characteristics on health care costs and to study the potential impact of biases concerning the use of real world data.

Summary of Background Data

Due to high direct and indirect societal costs of back pain there is a need for interventions that can assist in reducing the economic burden on patients and society.

Methods

All patients referred to a university based spine center insured at a major healthcare insurer in the the Netherlands were invited. Personal and disease related data were collected at baseline. Health care costs were retrieved from the healthcare insurer from two years prior to two years after intervention. Repeated Measures ANOVA's were calculated to study changes in healthcare costs after intervention. Multivariable regression analyses and cluster robust fixed effect models were applied to predict characteristics on health care costs. To study regression to the mean, a fixed effect model was calculated comparing two year prior to two years post intervention.

Results: In total 428,158 declarations during 4.6 years were filed by 997 participants (128,666 considered CBP-related). CBP-related costs significantly increased during the intervention period and reduced 2-years after the intervention. Total healthcare costs kept rising. The intervention was associated with a 21 to 34% ($p<0.01$) reduction in costs depending on the model used. Reduction in costs were related to being male and lower BMI.

Conclusions: This study suggests that reduction in CBP-related healthcare utilization in patients with complex CBP can be achieved after a multidisciplinary spine intervention. The results are robust to controlling for background characteristics and are unlikely to be fully driven by regression to the mean.

Keywords: Back Pain, Multidisciplinary Care, Healthcare Costs, health economic, spine, cohort, longitudinal, long term, regression to the mean, real world data

Level of Evidence: 4

Key Points

- Multidisciplinary spine intervention is associated with 34% ($p<0.01$) reduction in back related costs two years after intervention.
- Reduction in costs after intervention are related to being male and lower BMI.
- reduction in CBP-related healthcare utilization in patients with complex CBP can be achieved after a multidisciplinary spine intervention.
- The results are robust to controlling for background characteristics and are unlikely to be fully driven by regression to the mean.

Introduction

Chronic Back Pain (CBP) is responsible for the largest amount of years lived with disability world-wide with tremendous direct and indirect costs[1,2]. Intervention options are numerous but vary in effectiveness. While therapy effects on pain and quality of life in CBP are grossly known, the effects are usually studied during highly controlled cost-effectiveness trials. For example, multidisciplinary rehabilitation leads to moderate effect sizes in non-specific back pain[3,4], and surgery has better short term outcome in lumbar disc herniation compared to conservative care[5]. Pain interventions based on medication or injections may be effective in patients with severe radicular pain[6].

While these trials provide insight in the effects of the intervention on group level with selected patients, they may not be sufficiently capable to detect changes in healthcare costs in patients with complex CBP, who frequently suffer from co-morbidities and CBP-related sub-diagnoses[7]. For (cost)effectiveness trials, this undesirable heterogeneity between studies leads to impossibilities of pooling results in reviews[9] and may also lead to moderate effects of trials in general[8]. Hence, generalization of randomized trials is often limited because of strict use of 'narrow' inclusion criteria as well as to sampling bias. To properly control for heterogeneity, trials should control for deconditioning[10], altered central pain processing[11], comorbidity[12] and psychosocial barriers for recovery including depression[12], anxiety[13], or somatization[14]. To get a realistic impression of the magnitude and effects in healthcare costs of patients with complex CBP in real-world data, large cohorts with registry data may provide additional evidence[15]. These real-world data however, frequently suffer from biases related to regression to the mean, selection and confounding by indication.

While it is known that healthcare costs of patients with CBP are much higher compared to controls[12], a subset of patients with complex CBP may utilize a disproportionate amount of healthcare costs. It is unknown if healthcare costs of patients with complex CBP can be reduced post-intervention and which factors are predictive for a reduction in costs. Therefore, the aims of this study were to analyze the healthcare costs of patients with complex CBP two years prior until two years after tertiary multidisciplinary spine care. Study questions were: 1). Do patients with complex CBP reduce healthcare costs after a multidisciplinary intervention? 2). Which patient characteristics are associated with a reduction in healthcare costs after multidisciplinary intervention? 3). What were the effects of possible biases related to real-world data?

Materials and methods

Patients

Patients referred to X, were invited to participate. Patients came from urban and rural areas. In X, all inhabitants are insured. Patients were included between November 2011 and November 2014. To be eligible, patients were over 18 years of age, insured at healthcare insurer XX, and report CBP with or without radiation to leg(s) or arm(s) as primary pain site. As little exclusion criteria as possible were applied. Patients were excluded if they did not sign informed consent, when complaints were considered unrelated to their back or when patients were unable to fill out the baseline questionnaire.

Design

A before and after study design comparing healthcare costs from two years prior to two years post intervention.

Intervention

The X is a multidisciplinary center including neurosurgery, neurology, orthopedics, rehabilitation and anesthesiology. Interventions were chosen based on an evidence based medicine approach, including clinical expertise, research evidence and patient preferences[16]. Physician assistants performed initial triaging to one or a combination of medical specialists for an outpatient consultation. During the first visit to the spine center, if necessary, two to four specialists with different focus areas can assess the complaints in order to find the best treatment modality. If necessary, the case could be discussed afterwards in a multidisciplinary meeting, where other medical specialists (ie radiology, rheumatology, psychiatry) could be consulted. Next, all patients received information and advice to cope optimally with their complaints. In general, patients with multifactorial CBP were offered treatment in primary care (i.e. physiotherapy or exercise or posture therapy) or outpatient interdisciplinary rehabilitation including psychology, physiotherapy and occupational therapy in secondary or tertiary care. Surgery was offered to patients with specific CBP based on herniated disks or stenosis. Anesthesiology was provided to those patients with segmental root problems. Furthermor, patients could also be referred to primary care. When deemed indicated, combination of interventions could be deployed, following a stepped care approach. Information and advice was also provided in case of diagnostic purposes (second opinions).

Procedures

After referral, patients were sent an online or paper questionnaire. Prior to participation, patients received information about the purpose of this study and signed informed consent. The Medical Ethical Committee of the XXX provided a waiver for this study. Research was in accordance to the declaration of Helsinki and good clinical practice[17]. For reporting of the study, the consolidated health economic evaluation reporting standards (CHEERS) were applied and adapted for the design of the study[18].

Measurements

Baseline descriptive and health related characteristics of patients were gathered. The dependent variable in this study is healthcare costs.

Costs

Healthcare declarations were obtained from the healthcare insurer and were matched with the patients' clinical profile based on anonymous numbers. Based on the lists retrieved, the authors identified possible related healthcare costs to CBP and decisions on whether costs were concerned CBP-related were blinded to whether these had occurred prior or post-intervention. Whenever there was doubt on the relatedness of the declaration to the patients' CBP, it was decided to include the declaration (for example, a generic medicament prescription such as tramadol could be both CBP and not-CBP-related). CBP-related costs were divided into medical specialist care, allied care including physiotherapy, pharmaceutical care as regular medication by doctor's prescription, alternative care and supportive and assistive help: ergonomic house or mobility related adaptations including wound healing patches.
All secondary measures are presented in Table 1.

Analyses

Missing data

To avoid any biases in costs due to missing data, Multiple Imputation by Chained Equations (MICE) were used to impute missing data. Ten imputed datasets were made. Only full year declaration blocks per patient were imputed, because imputation of more detailed declarations (for example on missing data of alternative medicine declarations) was not possible, because of uncertainty if respective costs were actually made.

To answer the first study question, healthcare costs of patients were calculated according to five artificial time blocks ranging from two years prior to admission to two years after spine care (-2 and -1; respectively two and one year prior- and +1 and +2; one and two-year post-intervention) and one block representing the time between baseline and discharge. The time blocks were analyzed and the healthcare declarations made to the healthcare insurer were obtained and stratified in four blocks of one year each. All costs were corrected for inflation with 2017 as a reference year[26]. Additionally, differences over time per intervention were reported. Repeated Measures ANOVA's were used to analyze differences over time.

To answer study question 2, first, a linear regression was performed to identify relevant predictors that might be associated with the effect on healthcare costs. To study the intervention effect on costs, an intervention indicator was created, indicating whether a specific declaration was made pre (0) or post intervention (1). The intervention indicator was inserted as independent variable in the regression analysis. The cost reduction related to treatment might differ by individual characteristics such as, age, gender or disease or work-related characteristics because the context of patients may enable or disable a change in behavior. To test this, these characteristics were interacted with the treatment indicator in separate fixed effects models.

To study regression to the mean, a conservative adjusted sample was constructed. This adjusted sample included only the healthcare costs of two years prior compared to costs two years post intervention assuming that patients were not admitted to the intervention based on high healthcare costs two years prior to admission. A natural logarithmic transformation was applied to control for skewness. To study relevant interaction effects of the intervention effect and predictors, a fixed effect model was constructed. The interaction of every variable was tested in a separate fixed effect model. $P<0.05$ was considered statistically significant. Analyses were performed with SPSS-23 and STATA-15.

Results

Patients

A total of 1830 patients were admitted to the GSC and invited to participate in the study. Of these 997 patients were included. See Figure 1 for the flow diagram and reasons for exclusion. Included patients were on average 5.1 years older compared to non-participants ($p<0.01$) and women were included more compared to men ($p<0.01$). Descriptive statistics of the patient sample are presented in Table 2. The mean intervention time (GSC-0) was 201 days. The interventions in the total sample consisted of 546 patients receiving information and explanation, 203 patients followed interdisciplinary rehabilitation, 67 underwent surgery, 141 medication or injections, 37 a combination intervention of the above mentioned and for 3 patients the intervention could not be retrieved due to missing information in the patient record.

Study question 1: Healthcare Costs

Included patients filed a total of 428,158 declarations of which 128,666 were deemed CBP-related, during the 4.6 years they were followed, resulting in a total amount of €26.4 million of which €7.5 mln CBP-related. Some patients changed health insurer during the inclusion period, therefore 287 missing blocks of a total of 4703 (5.8%) declaration blocks were imputed. There appeared no significant differences in results between analyses in complete cases and imputed data.

Figure 2 graphically presents the mean healthcare costs per patient and mean CBP-related healthcare costs over the study period. Non CBP-related healthcare costs rose during the study period ($p<0.01$; Table 3 and Figure 2). CBP-related healthcare costs rose pre-intervention, are highest during GSC, decrease 2 years following GSC and were lower at that time compared to one-year pre-intervention. The majority of the reduction in CBP-related healthcare costs appeared to be due to a reduction in medical specialist care and allied care consumption ($p<0.01$) (Table 3). Results for the RM-ANOVA's show that there were no relevant increases in supportive devices although results are significant. GP costs two years prior to GSC are significantly lower compared to other years ($p<0.01$). Per intervention, similar patterns were observed, with highest CBP-related healthcare costs during the intervention and significant reductions in the post-intervention period. Post hoc tests revealed that differences between prior- and post-intervention blocks were non-significant (Table 3).

Study question 2: Patient and disease related factors predicting reduction of healthcare costs

Treatment is associated with a statistically significant reduction in CBP-related healthcare costs of 34% ($p<0.01$) (Table 4). The following values at baseline predicted higher healthcare costs per year: higher age (1% increase; $p<0.01$), female gender (42% increase; $p<0.01$), higher BMI (2% increase; $p<0.01$), lower EQ-5D (59% higher costs per point QoL; $p<0.01$), longer pain duration (20% increase with pain longer than 1 year; $p<0.01$) and comorbidity (25% increase; $p<0.01$).

Study Question 3: effects of bias

In the adjusted sample costs of two years prior to and to two years post-GSC are compared. Results show a statistically significant cost reduction of 21% ($p<0.01$), with similar predictors being significant (see Table 4).

Gender and BMI significantly interact with the treatment effect, leading to cost reduction. For example, a higher baseline BMI results in a smaller reduction in CBP-related healthcare costs (2% point smaller reduction per 1 kg/m^2 increase in BMI). In Table 5, the fixed effect model is presented.

Discussion

CBP-related healthcare costs of patients with complex CBP included in the GSC indicate that rising CBP-related healthcare costs pre-intervention decreased post-intervention to values lower than pre-intervention. This contrasts to the total healthcare costs, that kept rising over the years, before, during and post-intervention. This implies a cost-saving effect of multidisciplinary spine care on CBP-related costs, which was confirmed using several analytical methods. This study provides complimentary evidence that multidisciplinary spine care could be cost saving from an insurers' perspective, while we found no differences between intervention types. The results complement and point in the same direction as controlled studies, adding to the robustness of the observation that this type of care is beneficial from a health economic perspective. Additionally, this study is the first to fill an identified research gap[9].

Although all estimates indicate a reduction in CBP-related healthcare costs, the different methods produce different estimates of the percentage decrease in healthcare costs. The most conservative estimate, comparing two-year pre-intervention to two years post-intervention was calculated to control for regression to the mean. This led to a significant decrease of 21% for all costs, however the model would not only control for regression to the mean, but probably also partially bias the estimated intervention effect toward zero, leading to a too conservative estimate. The largest difference in healthcare costs was observed when comparing patients one and two years pre-intervention to patients one and two years post-intervention, which estimates a significant decrease of 34% for CBP-related costs. A previous study showed that the (self-reported) burden of patients with discogenic low back pain were high and reflect our data[27].

The major limitation of cohort studies compared to RCTs is the lack of a control group, which allows controlling for regression to the mean (in this case regression to the mean may indicate that patients get referred to the Groningen Spine Center on the basis of high healthcare costs one-year pre-intervention). Two theories are further explored. First, in the pre-interventional 11.5 years that patients report recurrent pain, patients encounter exacerbations of their chronic condition, leading to increase of costs prior to the intervention, which would lead to a cost reduction post intervention regardless of any intervention. Second, patients ran out of primary and secondary care options and are referred to tertiary care and have a stable declaration pattern over the years prior intervention. Lower costs post intervention would then imply true effect of the treatment. While the long term utilization patterns should be subject for further study, our conservative estimates in this study imply that effects are unlikely to be fully driven by regression to the mean and are indicative that back-pain related healthcare costs declines post-intervention. The mean estimates would lead to a decrease of 34%, which equals a decrease of €484 annually post intervention per patient. For the entire sample (N=997), this would imply a cost saving of €482,548, however this should be returned after the intervention because intervention costs were high.

It is remarkable to see the differences in cost patterns between total health care costs and CBP-related costs. There were no system or reimbursement changes during the study period that could explain the decrease in CBP-related costs. The reasons of the rising total health care costs (about 80% increase) can partially be explained by the following biases. First, inflation; estimated at 9%[26]. Second, in the Netherlands, health care costs keep rising in general; estimated at 26%[28]. Third, patients were 4.5 years older in the last block compared to the first; estimated at 19%[29]. Fourth, post hoc data analyses showed that there were some cases in which a dramatic increase in health care costs was observed, because of severe and very expensive treatments such as Pompe disease (increase costs > €300k), total hip replacement (€105k), heart surgery and cancer (multiple medicaments such as lenalidomide). We assume that patients referred to spinal treatment are currently not in active phases of other life threatening disease that requires immediate attention. The first three biases explain 54% of the 80% rise in total health care costs. Against a strong trend of rising total health care costs, the CBP-related costs decreased, which would suggest that the effect of CBP-related costs of the intervention could even be substantially larger.

A particular strength of this study was the use of real world data and the long follow-up period. This is among the first studies to report on real-world data. Objective data instead of self-report data was used which excludes recall bias. The data from this real world cohort reflects costs savings derived from RCTs[9], however, is much more applicable to the broad population of patients with CBP. Another strength was that declarations of a large group of almost 1000 persons were retro- and prospectively retrieved from the healthcare insurer with little missing data (5.5%). As previously stated, the main limitation of this study is the study design, because no control group was available that received usual or no care. Furthermore, unknown confounders may have not been controlled for.[30] Further research should aim at comparing real world data with a relevant control group to provide further evidence on the economic and clinical effect of multidisciplinary spine care[31]. A second limitation is that this study focused solely on direct medical healthcare costs from the insurance perspective. In a previous study, it was concluded that approximately 87% to 89% of total societal burden was related to losses in productivity[32]. This means that the results from this study may underestimate the total societal burden.

Conclusion

The results of this study indicate that multidisciplinary spine intervention decreases back-pain related healthcare costs for 34%. BMI and gender are associated with a decrease in healthcare costs post-intervention. Controlling for biases related to real world data led to a significant decrease of 21%. These results are valuable from the perspective of the patients, government, health insurers and clinicians.

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Figure 1, flow diagram

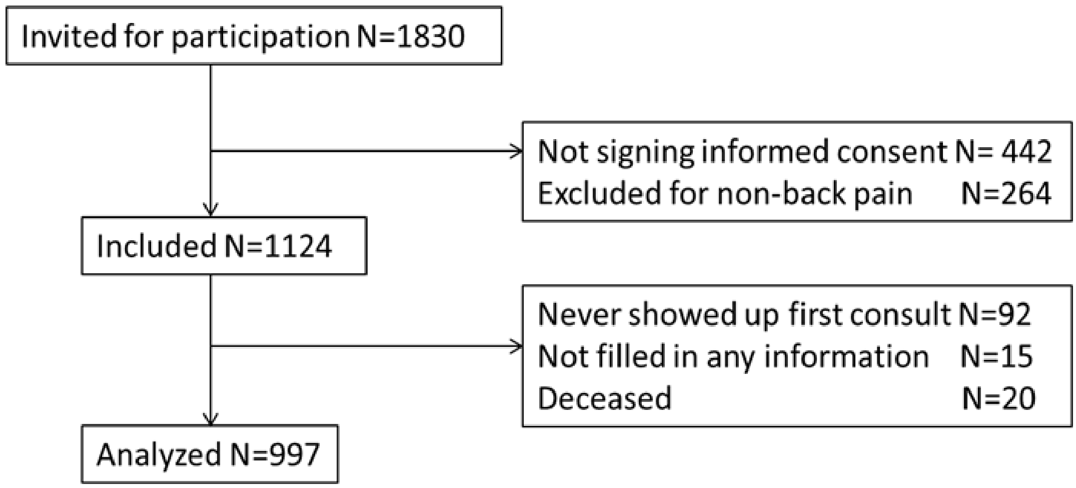

Figure 2: CBP-related and total costs per patient during the 4.6 years of analyses

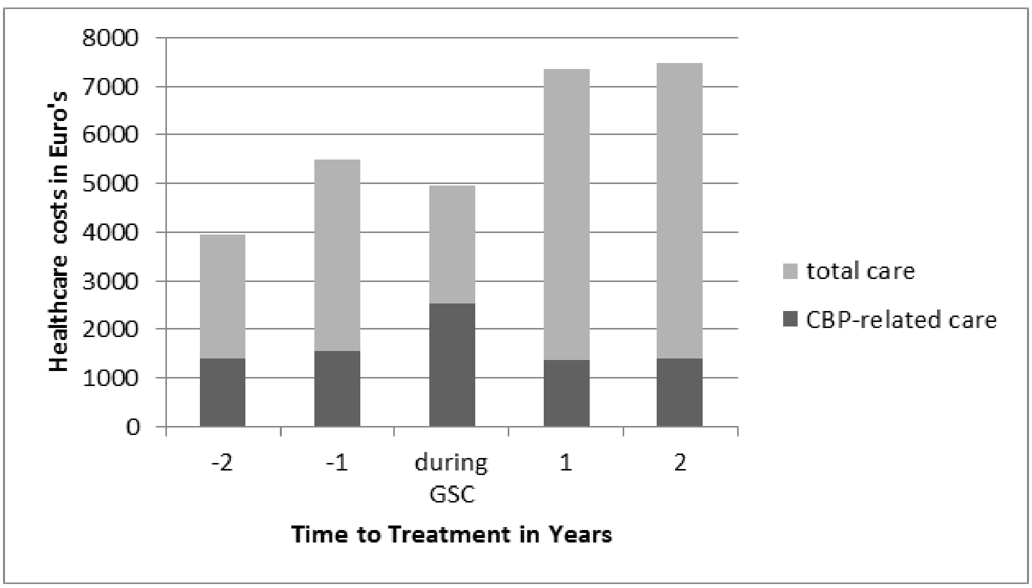

Table 1. Secondary measures used in study

Domain	Questionnaire	Item	Descriptor
Personal		sex	0=female, 1=male
		age	Age in years
		Body mass index	BMI in kg/m^2
		Financial worries	0=not present, 1 present
		Education	0=no education to lower professional education; 1=higher professional education and higher
Disorder related	EuroQol 5D-3L	6 items	Five questions are categorical (1-3 scale) and one question is on interval level (NRS 0-10)[20]. The Dutch language version of the EQ-5D was used [21]. The Dutch utility index was used[21]. The scale of the Dutch Tariff ranges from -0.33 to 1.00 with higher scores reflecting higher QoL.
	Pain numeric rating scale (NRS)	1 item	11-point numeric rating scale (NRS), ranging from 0 (no pain) to 10 (worst pain ever). Reliability and validity of the Pain NRS is sufficient[22].
	Pain duration	1 item	0=shorter than one year; 1=longer than one year.
	Comorbidity	List of relevant comorbidities + open question	0=no comorbidity; 1=comorbidity
Work-related	Job satisfaction	Question 17 of Örebro musculoskeletal pain questionnaire	if you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job on a 0-10 scale?[23,24].
	Physical Workload	Question eight of the Örebro musculoskeletal pain questionnaire	(is your work heavy or monotonous on a 0-10 scale?)[23,24]
Psychological	Mental health	Rand-36 domain for emotional wellbeing[25]	
	Coping skills	question 12 of the Örebro musculoskeletal pain questionnaire	based on all things you do to cope, or deal with your pain, on an average day, how much are you able to decrease it on a 0-10 scale?[23,24]

Table 2. Patient characteristics at baseline (N=997)

Name	Factor	Mean	Sd/%
Personal and demographic	Age	51.7	14.4
	Gender (male/female) (N)	414/583	42%
	Education high (high/low) (N)	276/502	35%
	Financial worries (yes/no) (N)	134/863	13%
	Body mass index	27.1	5.1
Work-related	Job satisfaction (0-10)	6.7	2.6
	Physical workload (0-10)	4.2	3.1
Pain condition	Pain intensity (0-10)	7.0	1.6
	EQ-5D (-0.33 – 1.0)	0.47	0.3
	Comorbidity present (yes/No) (N)	419/578	42%
	Pain duration (<12 months=0;>12 months=1) (N)	303/668	31%
Psychological	Mental health (0-10)	6.9	1.9
	Coping skills (0-10)	4.0	2.7

Sd: standard deviation

Table 3. Total CBP-related costs per year in k€ (N=997)

Type of care	-2 Years	-1 Year	During GSC	+ 1 Year	+ 2 Years	F(df)	p
Medical specialist (k€)	619.0	766.8	2039.9	549.7	475.1	115.9(2.9)	<0.01[c,d]
Allied (k€)	193.7	373.7	160.8	303.0	238.9	66.5(3.7)	<0.01[a,b,c,d]
Pharmaceutical (k€)	111.7	141.1	101.3	155.9	156.6	1.1 (1.2)	0.31
General Practitioner (k€)	58.7	88.7	45.3	82.3	80.6	69.6(3.8)	<0.01[a,b,c,d]
Supportive devices (k€)	39.7	28.5	21.8	49.5	78.2	8.2(2.6)	<0.01[b,c,d]
Alternative medicine (k€)	16.2	27.3	11.1	23.4	18.6	8.2 (3.8)	<0.01[a,d]
Other CBP-related (k€)	89.1	117.9	88.1	119.0	115.6	N/A	N/A
Total CBP-related costs (k€)	1128.1	1544.0	2468.3	1282.8	1163.5	38.9 (4)	<0.01
Information cohort (N=546; €)	1241	1426	1269	1254	1325	0.96 (3.1)	0.41[c]
Rehabilitation cohort (N=203; €)	1209	1502	4457	1304	1147	89 (2.7)	<0.01
Surgery cohort (N=67; €)	2040	2065	5924	2145	1942	18.6 (2.6)	<0.01
Medication/injection cohort (N=141; €)	1664	1879	2637	1592	1576	4.8 (3.1)	<0.01
Combination of above (N=37; €)	2025	1953	4717	1532	1900	9.1(2.8)	<0.01
Total healthcare costs (k€)	3644.6	5402.4	4821.4	7040.7	6716.0	17.4 (4)	<0.01[a,b,c,d]

F: F-value; df: degrees of freedom; p:p-value; [a,b,c,d] : Posthoc LSD corrected test: [a]two years pre intervention significantly differs from 1 Year post; [b]Two years pre intervention significantly differs from 2 Years post; [c]One year pre intervention significantly differs from 1 year post; [d]One year pre intervention significantly differs from 2 years post. GSC: Groningen Spine Center. Costs per intervention cohort represent CBP-related costs and per patient because of different sample sizes.

Table 4: Predictors on CBP-related healthcare costs (N=997):

Name	**Factor**	**CBP-related costs**	Adjusted sample
		Beta (SE)	Beta (SE)
	Intervention effect[1]	-0.34** (0.05)	-0.21** (0.07)
Personal and demographic	Age	0.01** (<0.01)	0.01** (<0.01)
	Gender (male=1)	-0.42** (0.08)	-0.45** (0.10)
	BMI	0.02** (<0.01)	0.02** (<0.01)
	Education (high =1|)	0.07 (0.09)	0.02 (0.11)
	Financial worries	-0.06 (0.10)	-0.10 (0.15)
Psychological	Mental health	-0.04 (0.04)	-0.04 (0.05)
	Coping skills	<0.01 (0.01)	<0.01 (0.02)
Work-related	Job satisfaction	<0.01 (0.01)	<0.01 (0.02)
	Physical workload	<0.01 (0.01)	<0.01 (0.02)
Pain condition	Pain intensity	<0.01 (0.02)	0.02 (0.03)
	EQ-5D	-0.59** (0.14)	-0.46* (0.19)
	Comorbidity	0.25** (0.07)	0.27** (0.09)
	Duration (> 1 year=1)	0.20* (0.07)	0.34** (0.10)

/ statistical significance at the 5% and 1% level. Standard errors between brackets. [1]Intervention effect: costs made prior to (0) or post (1) intervention. Back pain related costs represent all costs declared prior or post intervention. Adjusted sample presents all costs two years prior to two years post intervention. Nb. Cost Data is log transformed and inflation corrected.*

Table 5. Interaction effects of predictors on the treatment effect (N=997)

Name	Factor	Intervention Effect[1]	Interaction Term
		Beta (SE)	Beta (SE)
Personal and demographic	Age	-0.67** (0.18)	0.01 (<0.01)
	Gender (Male)	-0.24** (0.06)	-0.23* (0.10)
	BMI	-0.99** (0.24)	0.02** (<0.01)
	Education high	-0.33** (0.05)	-0.04 (0.11)
	Financial worries	-0.26** (0.07)	-0.15 (0.11)
Work-related	Job satisfaction	-0.32** (0.12)	<0.01 (0.02)
	Hard work	-0.28** (0.07)	-0.01 (0.01)
Psychological	Mental health	-0.41* (0.20)	0.02 (0.04)
	Coping skills	-0.36** (0.08)	<0.01 (0.02)
Pain condition	Pain intensity	-0.38* (0.20)	<0.01 (0.03)
	EQ-5D	-0.31** (0.09)	-0.05 (0.15)
	Comorbidity	-0.40** (0.06)	0.15 (0.09)
	Duration	-0.29** (0.08)	-0.07 (0.09)

*Note: */** stands for statistical significance at the 5% and 1% level. [1]Intervention effect: costs made prior to or post intervention*