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ORIGINAL ARTICLE

No difference in 9-year outcome in CLBP patients randomized to lumbar fusion versus cognitive intervention and exercises

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Abstract
Purpose To compare the 9-year outcome in patients with chronic low back pain treated by instrumented lumbar fusion versus cognitive intervention and exercises.
Methods The main outcome measure was the Oswestry Disability Index (ODI). Secondary outcome measures included pain, fear-avoidance beliefs, trunk muscle strength, medication, and return to work.
Results One-third of the patients randomized to cognitive intervention and exercises had crossed over and been operated and one-third of the patients allocated to lumbar fusion had been re-operated. The intention-to-treat analysis detected no differences between the two groups. The mean adjusted treatment effect for ODI was 1.9 (95 % CI −7.8 to 11.6). Analysed according to the treatment received, more operated patients used pain medication and were out of work.
Conclusions The outcome at 9 years was not different between instrumented lumbar fusion and cognitive intervention and exercises.

Keywords Randomized clinical trial · Low back pain · Long-term outcome · Operative · Physical therapy

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Background

The use of surgery for treatment of non-specific low back pain has increased considerably over the past two decades [1]. Four randomized trials have compared instrumented lumbar fusion with conservative treatment [2–5]. Fritzell et al. [2] reported that patients randomized to lumbar fusion had improved back-specific disability at 2-year follow-up compared to patients who received unstructured community care. No difference has been reported in the trials comparing lumbar fusion and cognitive behavioural intervention after 1- or 4-year follow-up [3–6]. In a recent cohort study of workers operated with lumbar fusion, it was reported that the re-operation rate was 25 %, opioid use 76 %, and return to work only 26 % [7]. Similar results were described by Brox et al. [6] in a 4-year follow-up study.

The main objective of the present study was to compare primary and secondary outcome measures in patients randomized to lumbar fusion or cognitive intervention and exercises 9 years following treatment. The evaluation had a specific focus on the number of patients who changed treatment group (crossover), had re-operations, returned to work, and used pain medication.

Methods

Study design

The present study is a 9-year follow-up of two randomized controlled trials conducted to compare instrumented lumbar fusion and cognitive intervention and exercises for chronic low back pain (CLBP) [3, 5]. The two studies were merged before the 4-year follow-up [6].

Patients

During the period 1997–2000, patients with CLBP were recruited from the department of orthopaedic surgery, neurosurgery, and physical medicine and rehabilitation from all regions of Norway. Clinicians at the referral hospitals performed a brief examination of patients with respect to inclusion and exclusion criteria and informed eligible patients about the trial. All patients underwent plain radiography; in addition, most of the patients had computer tomography (CT) or magnetic resonance (MRI) at inclusion. A research physiotherapist coordinated the study and verified eligibility.

The criteria for inclusion at baseline were patients aged 25–60 years, with reported low back pain for at least 1 year, a score of 30 out of 100 points on the Oswestry Disability Index (ODI) [8], and degenerative changes at the L4–L5 and/or L5–S1 on plain radiographs. One of the merged studies excluded patients with previous disc surgery [3], while the other did not [5]. The criteria for exclusion included widespread myofascial pain, spinal stenosis with reduced walking distance and neurologic signs, disc herniation or lateral recess stenosis with clinical signs of radiculopathy, inflammatory disease, previous spinal fracture, the pelvic girdle syndrome, generalized degenerative changes on plain radiograph examination, serious somatic or psychiatric disease that excluded either one or both treatment alternatives, registered medical abuse, or reluctance to accept one or both of the treatment regimens of the study. All eligible patients were given oral and written information about the study and the two interventions.

Patients were re-contacted by mail and invited to participate in the long-term follow-up study. The Ethics Committee for Medical Research in health region I of Norway approved the study.

Outcome measures

The primary outcome measure was the Norwegian version of the original ODI (version 1.0) to evaluate condition-specific disability and pain [8, 9]. This score has ten questions about pain and disability and ranges from 0 % (no pain and disability) to 100 % (worst possible pain and disability). Measurement error in a single patient is 12 % [10–13].

Secondary outcome measures included back and leg pain [2], global back disability question for the assessment of patients' overall rating [10], fear-avoidance beliefs for physical activity (FABQ-PA), [14], life satisfaction [15], fingertip–floor distance [16], isokinetic trunk muscle strength [17], complications, crossover and re-operation, use of pain medication and work status. Return to work included full-time and part-time work.

The following additional questions were included at the 9-year follow-up: Are your back problems better after compared to before the treatment? It had two response alternatives: yes/no; How satisfied are you with the treatment for your back problem? It had five response alternatives: very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, and very dissatisfied; and questions about treatment taken after the last follow-up. Additional surgery was verified from medical records. An experienced physiotherapist, who had conducted the tests both at baseline and at 1-year follow-up, supervised the tests of isokinetic trunk muscle strength [17, 18].

At long-term follow-up, the patients were examined by a specialist in physical medicine and rehabilitation (AF) and a physiotherapist (IH). None of them were engaged in the treatment of patients.

Randomization

The randomization procedure has been described previously [3, 5, 6]. Treatments were started within 3 months after randomization.

Treatments

Lumbar fusion consisted of posterolateral autologous bone transplantation and transpedicular screw fixation of the L4–L5 and/or L5–S1 segments. Physiotherapists at the respective departments provided advice about recommended daily activities during the first 3 months after surgery. The surgeons conducted follow-up consultations with each patient at 3 and 6 months and prescribed physiotherapy, including exercises. Information about content and compliance of postoperative physiotherapy in the lumbar fusion group after discharge from hospital are based on a standardized question answered by the patients at the 1-year follow-up. After discharge from the hospital or the patient's hotel, the lumbar fusion group had a median number of 32 physiotherapy sessions during the first year.

The cognitive intervention and exercises programme has been previously described [3, 5]. It included 1 week at the outpatient clinic, 2 weeks at home, followed by 2 weeks at the outpatient clinic. The programme was conducted by physiotherapists and a specialist in physical medicine and rehabilitation. Patients were divided into treatment groups consisting of four to seven patients. Three daily workouts were performed: aerobics or outdoors activities, water gymnastics, and individual or group exercises. The intensity of the physical activities was gradually increased during the last 2 weeks. The average duration of the rehabilitation programme was 25 h per week. Patients were challenged in their thoughts about, and participation in,

physical activities previously labelled as not recommended including jumping, lifting, and ball games. The essential message in the cognitive intervention was that the patients could not do any harm to their back by participating in daily activities (i.e. vacuum cleaning, ironing, gardening, etc.). Endurance and coordination exercises were recommended, not necessarily with the goal of increasing aerobic capacity and trunk muscle strength, but to allow the patients to gain confidence towards engaging in ordinary activities of daily life. Individual goals for the rehabilitation process were established based on the patients' answers to a comprehensive questionnaire (thoughts and feelings) and their test results (physical function and behaviour). After the programme was fulfilled, the cognitive intervention and exercise group had a median of zero physiotherapy sessions during the first year.

Statistical analysis

Estimation of sample size has been reported previously [3, 5]. Results were analysed both with an intention-to-treat- and with an as-treated approach. Linear regression

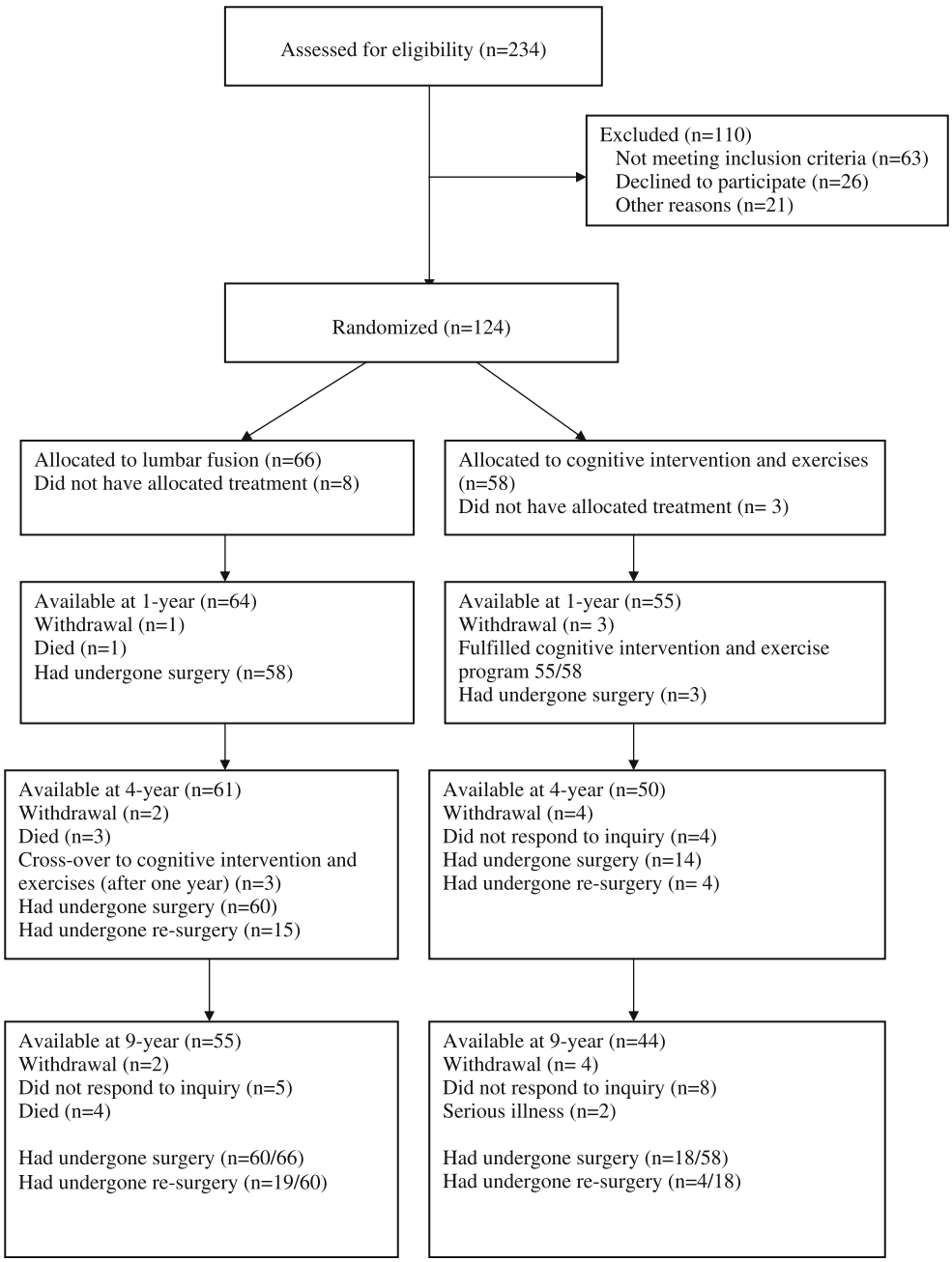

Fig. 1 Flowchart of patients included in the present study

(ANCOVA) with adjustments for gender, age, fusion, previous discectomy, and baseline scores was used to detect treatment effects between interventions at 9 years. Mean adjusted differences between groups (95 % CI) in those who attended the long-term follow-up are reported. A mixed between-within subjects analysis of variance (SPANOVA) was conducted to compare the time course for primary and secondary outcome measures in both treatment groups. Scores for ODI and back pain were assessed across four time periods: at baseline, and 1-, 4-, and 9-year follow-up. Ordered variables were analysed with a Mann–Whitney *U* test. Categorical variables (patients' overall rating, work, and medication) were dichotomized and χ^2 tests were conducted to compare differences between the two groups. Logistic regression, with adjustments for age, gender, lumbar fusion, previous discectomy, and baseline scores, was used to calculate OR (95 % CI). Analyses were carried out with the use of SPSS software, version 18.0.

Results

Patients

The recruitment and follow-up of study participants are shown in Fig. 1. Of 124 patients included at baseline, 99 (80 %) attended the long-term follow-up: 55 randomized to lumbar fusion and 44 to cognitive intervention and exercises. In the surgical group, 90 % had undergone surgery at 9 years, and the corresponding number for the cognitive intervention and exercise group was 31 %.

Table 1 Baseline characteristics of all patients included and the 99 patients followed up at 9 years

	Lumbar fusion		Cognitive intervention and exercises	
	Baseline ($n = 66$)	Long term ($n = 55$)	Baseline ($n = 58$)	Long term ($n = 44$)
Mean age (years)	42.7 ± 8.0	43.0 ± 8.1	42.4 ± 8.0	42.6 ± 7.9
Men/women (%)	27/39 (41/59)	19/36 (35/65)	29/29 (50/50)	19/25 (43/57)
Duration of symptoms in years	8.9 ± 7.9	8.7 ± 7.6	9.6 ± 7.4	9.8 ± 6.7
Married/living together	57 (86)	47 (85)	49 (81)	38 (86)
Occupational education <3 years	45 (68)	39 (71)	38 (66)	28 (64)
Work status				
Working	9 (14)	9 (16)	9 (16)	7 (16)
On sick leave	14 (21)	13 (24)	16 (28)	12 (27)
On rehabilitation	29 (44)	21(38)	22 (38)	17 (39)
Disability pension	10 (15)	8 (15)	10 (17)	7 (16)
Other	4 (6)	4 (7)	1 (2)	1 (2)
ODI	44.5 ± 10.7	44.5 ± 10.8	44.2 ± 11.0	44.4 ± 11.2
Back pain (0–100) (worst possible)	63.0 ± 14.7	62.4 ± 14.4	64.6 ± 12.5	63.2 ± 12.8
Comorbidity	24 (36)	20 (36)	18 (31)	13 (30)
Taking analgesics daily or weekly	40 (61)	33 (60)	40 (69)	31 (70)
Smoking	36 (55)	28 (51)	30 (52)	21 (48)

Values are mean ± SD or number of patients (%)

Table 2 Comparison of changes observed at the previous follow-up in patients who attended long-term follow-up and in dropouts

Mean change in outcome from baseline to 4-year or previous follow-up are given	Lumbar fusion		Cognitive intervention and exercises	
	Had long-term follow-up ($n = 55$)	Dropouts ($n = 11$)	Had long-term follow-up ($n = 44$)	Dropouts ($n = 14$)
ODI	16.3 ± 20.3	4.9 ± 21.0	12.4 ± 17.7	9.8 ± 19.7
HSCL25	0.24 ± 0.67	0.14 ± 0.48	0.25 ± 0.73	0.10 ± 0.55
FABQ physical activity	3.9 ± 7.7	1.8 ± 5.3	8.1 ± 7.2	2.6 ± 6.5
Back pain	21.6 ± 27.2	10.3 ± 25.7	17.0 ± 24.6	19.1 ± 24.2
Lower limb pain	15.4 ± 30.4	−3.3 ± 17.7	5.9 ± 22.7	9.4 ± 31.0

Mean ± SD are given

Return to work and health-care utilization

Nineteen (35 %) of the patients randomized to lumbar fusion were working full- or part time at long-term follow-up, compared to 16 (36 %) in the cognitive intervention and exercises group ($p = 0.85$). Thirty-five (64 %) patients in the lumbar fusion group were out of work compared to 26 (59 %) in the cognitive intervention and exercise group ($p = 0.53$). Nineteen (35 %) patients randomized to lumbar fusion reported that they had visited a physician and 14 (25 %) had received physiotherapy the year before the 9-year follow-up. In the cognitive intervention and exercise group, 19 (43 %) reported visits to a physician and 13 (30 %) had received physiotherapy.

Dropout rate, crossover, complications, and re-operations

Patients who did not attend the 9-year follow-up were not different from dropouts at baseline or the latest follow-up before 9 years (Tables 1, 2). Three patients randomized to fusion crossed over and had cognitive intervention and exercises after 1-year follow-up. At the 4-year follow-up, 60/66 patients had undergone surgery and 15/60 had undergone re-surgery. Between 4 and 9 years, the implant

Table 3 Intention-to-treat analyses at 9-year follow-up

Outcome	Lumbar fusion ($n = 55$)	Cognitive intervention and exercises ($n = 44$)	Adjusted treatment effect (95 % CI)[a]
Primary outcome			
Oswestry Disability Index			
Baseline	44.5 ± 10.8	44.4 ± 11.2	1.9 (−7.8 to 11.6)
9-year follow-up	24.3 ± 19.5	24.6 ± 18.3	
Secondary outcome			
Back pain			
Baseline	62.4 ± 14.4	63.2 ± 12.8	1.2 (−11.6 to 14.0)
9-year follow-up	37.3 ± 24.8	40.4 ± 26.3	
Leg pain			
Baseline	46.8 ± 24.9	44.6 ± 22.7	−5.5 (−17.8 to 6.8)
9-year follow-up	25.9 ± 25.9	32.6 ± 27.5	
Emotional distress[b]			
Baseline	1.9 ± 0.5	1.9 ± 0.6	0.04 (−0.2 to 0.2)
9-year follow-up	1.4 ± 0.4	1.4 ± 0.4	
Life satisfaction[c]			
Baseline	5.2 ± 2.2	4.7 ± 1.8	−0.5 (−1.5 to 0.6)
9-year follow-up	7.1 ± 2.0	7.2 ± 1.9	
Fear-avoidance beliefs physical activity[d]			
Baseline	13.4 ± 4.9	16.0 ± 5.0	−1.3 (−4.3 to 1.6)
9-year follow-up	6.9 ± 6.4	5.8 ± 5.6	
General function score (GFS)			
Baseline	37.4 ± 19.7	41.5 ± 18.5	−0.9 (−10.3 to 8.6)
9-year follow-up	17.4 ± 17.2	18.9 ± 20.8	
Better than before treatment[e]	34 (62)	18 (41)	OR 2.2 (1.0 to 5.1)*
Trunk muscle extension 60°/s (Joule)			
Baseline	493 ± 355	418 ± 292	−7.5 (−192 to 177)
9-year follow-up	507 ± 340	475 ± 341	

Values are mean ± SD and mean adjusted differences (95 % CI) between lumbar fusion and cognitive intervention and exercises

[a] Adjusted for age, gender, fusion, and previous discectomy

[b] Emotional stress ranges from 1 to 4, with lower scores indicating less severe symptoms

[c] Life satisfaction ranges from 1 to 10, with higher scores indicating better life satisfaction

[d] Fear-avoidance beliefs for physical activity ranges from 0 to 24, with higher scores indicating stronger beliefs

[e] Values are numbers (%)

* $p = 0.067$ (Fischer's exact test)

was removed in four patients in the surgical group, resulting in re-operation in 19/60 patients.

Three of the 58 patients randomized to cognitive intervention and exercises did not have the allocated treatment. At the 4-year follow-up, 14/58 patients had undergone surgery and 4 patients had re-surgery. Four patients were operated between 4 and 9 years: two for spinal stenosis; one had disc prosthesis for recurrent pain; one patient, who did not have the allocated intervention, had instruments removed. A total of 18/58 patients had operation (Fig. 1). The reasons for re-operations were removal of instrumentation because of persistent pain. There were no infections.

Main treatment effects

The adjusted treatment effect for ODI between fusion and cognitive intervention and exercises was 1.9 (−7.8 to 11.6) (Table 3). Figure 2 shows the ODI score from baseline to long-term follow-up. There was no significant interaction between intervention and time. There was a substantial main effect for time, Wilks $\lambda = 0.50$, F (3.93) = 31.2; $p < 0.001$, partial $\eta^2 = 0.50$, with both groups showing a reduction in ODI score from baseline to long-term follow-up. There was a reduction in ODI score within both groups from 4- to 9-year follow-up ($p < 0.05$). The main effect comparing the two treatments from 4- to 9-year follow-up was not significant.

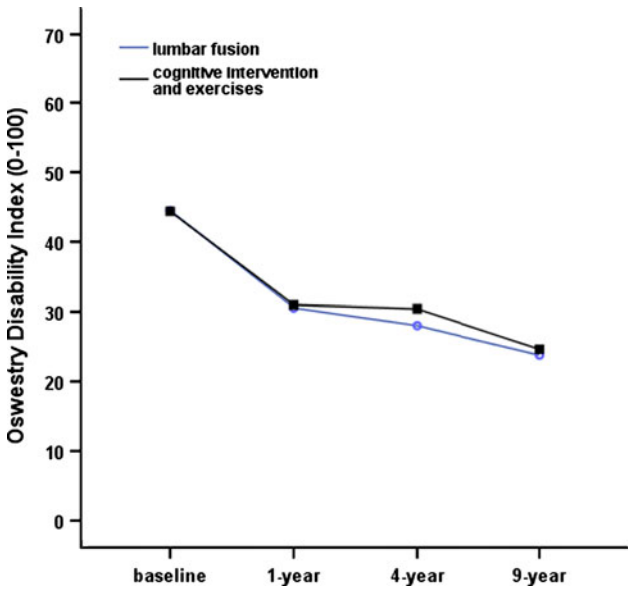

Fig. 2 Change in ODI from baseline to 9-year follow-up in the two randomized groups

Secondary outcome

Secondary outcomes were not significantly different between lumbar fusion and cognitive intervention and exercises at 9-year follow-up (Table 3).

Both groups reported significantly ($p < 0.01$) less back and leg pain, less fear-avoidance beliefs, less emotional distress, and improved general function score at 9 years compared to baseline. No differences between the two groups were found for overall rating and satisfaction with treatment results.

Sensitivity analyses

Sixty-three of the patients attending the 9-year follow-up had been operated and 36 were not operated. More operated patients (68 vs. 42 %) were out of work at the 9-year follow-up compared to those who had cognitive intervention and exercises and were not operated (adjusted OR 3.0; 95 % CI 1.3–7.4, $p = 0.013$). Pain medication was taken daily or weekly by 44 % treated by lumbar fusion versus 17 % of the patients in the cognitive intervention and exercise group (adjusted OR 4.0; 95 % CI 1.5–11.0; $p = 0.005$).

More operated patients reported that their back problems were better compared to pre-treatment (adjusted OR 2.8; CI 1.2–6.5, $p = 0.02$) (Table 4).

Seventeen percent were dissatisfied after surgery compared with 3 % in the cognitive intervention and exercise group ($p = 0.03$).

Table 4 Patient overall rating [given by number of patients (%)] by the Global Back Disability Question, according to intention to treat and to the treatment received (lumbar fusion vs. cognitive intervention and exercises and no fusion)

"How will you rate your back today?"	Intention to treat		As treated	
	Lumbar fusion ($n = 55$)	Cognitive intervention and exercises ($n = 44$)	Lumbar fusion ($n = 63$)	Cognitive intervention and exercises and no fusion ($n = 36$)
Excellent, no or unimportant complaints	10 (18)	4 (9)	12 (19)	2 (6)
Good, occasionally bothered by back pain	14 (26)	13 (30)	18 (29)	9 (25)
Fair, some back pain and limited function	15 (27)	11 (25)	12 (19)	14 (39)
Poor, unchanged, considerable complaints and severe disability	16 (29)	15 (34)	20 (32)	11 (31)
Miserable, worse, not self-reliant in activities of daily living	0	1 (2)	1 (2)	0

Discussion

There were no differences in primary or secondary outcomes at the 9-year follow-up between patients randomized to lumbar fusion or cognitive intervention and exercises. The long-term results are largely consistent with previously reported results at 1- and 4-year follow-up [3, 5, 6].

A difference in return to work in favour of the cognitive intervention and exercises was found in the as-treated analysis. This is in agreement with the results from Nguyen et al. [7], who in a large cohort study showed that patients on worker's compensation, who had undergone lumbar fusion, had significantly higher permanent disability rates compared to non-operated controls randomly selected from the same database. Return to work (RTW) is an important outcome when treating CLBP patients, because RTW is an objective personal health outcome. Multiple studies have shown that being out of work is associated with poor health [7]. There may be different explanations for the higher disability rate in the operated patients, but our interpretation is that disability pension may be easier to achieve when operated, because the claim adjuster may consider lumbar fusion to represent the end stage of treatment. We can, however, not conclude that fusion is inferior to cognitive intervention and exercises for return to work, because results in the intention-to-treat analyses were not significant.

The as-treated analysis in the present study showed that patients operated with lumbar fusion have an increased and higher use of pain medication (opioids) compared to patients who were not operated. These findings are in accordance with previous published studies [7, 19]. One possible explanation for this increased use of medication may be that patients have persistent, disabling low back pain for years in spite of the surgery [19]. The operated patients may experience more pain because of the surgical procedures through disruption of anatomy and biomechanics, leading to flat-back syndrome or adjacent level degeneration, kyphosis, or scoliosis [20], or they may have been habituated to addictive medication. No difference between groups was found in the intention-to-treat analysis, which makes a conclusion about the cause for the observed medication consumption in the operated patients difficult.

There are limitations to the present study. One-third of the patients allocated to the cognitive intervention and exercise group crossed over and were operated after the 1-year follow-up.

The high number of crossover patients and the patients who did not attend long-term follow-up make a firm scientific conclusion about results at 9 years difficult, but on comparing the last observed data of those who did not attend the 9-year follow-up with those who attended we found only minor differences between the randomized groups suggesting that analyses at 9 years were not biased.

The study has been criticised for lack of power to detect important clinical differences [21, 22]. Nevertheless, the study had enough power to detect significant differences for secondary outcomes at the 1- and 4-year follow-up [3, 5, 6]. The observed difference for the primary outcome is much smaller than the study was designed to detect, although the upper 95 % confidence level is about the size of minimal clinically important difference (MCID).

The main strength of the present study is that this is the first long-term follow-up of a randomized trial to compare lumbar fusion and non-operative treatment in non-specific or degenerative CLBP. The primary and secondary outcomes of the present study are validated and the follow-up rate is relatively high for long-term follow-up, with 80 % attendance.

In conclusion, patients randomized to lumbar fusion did not report better long-term outcome compared to cognitive intervention and exercises. Both randomized groups reported less pain and better function at 9 years compared to baseline (and 1-year follow-up), but more operated patients used pain medication and were out of work. However, more patients operated reported that they were better than before surgery.

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Conflict of interest None.

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