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6

Cost-effectiveness of early rehabilitation after lumbar disc surgery: the REALISE trial

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Oosterhuis T, Ostelo RW, van Dongen JM, Peul WC, de Boer MR, Bosmans JE, Vleggeert-Lankamp CL, Arts MP, van Tulder MW. Effectiveness and cost-effectiveness of early rehabilitation after lumbar disc surgery (REALISE): a randomised controlled trial. Submitted

Abstract

Background: for patients who underwent lumbar disc surgery for herniated discs, the two most common options for postoperative management are referral for rehabilitation starting immediately after discharge from the hospital or no referral. A direct comparison of the cost-effectiveness of these two strategies is lacking.

Objective: to conduct a cost-effectiveness analysis comparing rehabilitation after lumbar disc surgery starting immediately after discharge with no referral for rehabilitation.

Methods: 169 patients who underwent lumbar discectomy were randomly assigned by use of computer-generated blocks to the rehabilitation or control group. At baseline, 3, 6, 9, 12 and 26 weeks postoperatively, global perceived effect, functional status, pain intensity and health-related quality of life were measured. Cost data were collected at 6, 12 and 26 weeks from a societal perspective. Missing data were multiply imputed. Incremental cost-effectiveness ratios, cost-effectiveness planes and cost-effectiveness acceptability curves were estimated using bootstrapping. To test the robustness of the results various sensitivity analyses were conducted.

Results: mean total societal costs were €6486 (SD 626) and €6790 (SD 957) for the rehabilitation and control group, respectively. At 26 weeks, no significant cost and effect differences were found. For health-related quality of life, the maximum probability for the intervention to be cost-effective was 0.75 at a willingness-to-pay of €32,000/QALY. Irrespective of the willingness-to-pay, the maximum probabilities of cost-effectiveness for functional status, leg or back pain and recovery were 0.68, 0.70 and 0.70, respectively.

Conclusion: from the societal perspective rehabilitation after lumbar disc surgery starting immediately after hospital discharge was not cost-effective compared to no referral for early rehabilitation.

Introduction

In the Netherlands, the incidence of sciatica is approximately 85,000 cases per year [1, 2].The direct and indirect costs of patients suffering from sciatica approximate 1.2 billion Euros per year [1]. It is estimated that about 12,000 operations for herniated lumbar discs are performed in the Netherlands each year [2, 3]. The two most common options for management after discharge are referral or no referral for early rehabilitation [4]. Several randomised controlled trials investigated the effectiveness of rehabilitation following lumbar disc surgery [5]. Exercise programs starting 4–6 weeks post-surgery are slightly more effective in improving physical function and pain than no treatment, with high intensity training being more effective than low intensity training. However, high quality studies assessing the effectiveness of immediate postoperative interventions are lacking [5].

Healthcare decision makers are increasingly being faced with decisions about which treatments to reimburse with the limited resources available. Economic evaluations provide information on the relative cost-effectiveness of two or more interventions. Economic evaluations identify, measure, value and compare the costs and consequences of these interventions. Consequences can be expressed as clinical effects, utilities or financial benefits. Even though economic evaluations are increasingly being conducted to inform healthcare decision makers, data on the cost-effectiveness of postoperative management after lumbar disc surgery is scarce. Up until now only one trial reported that there were no differences in costs and outcomes between rehabilitation and no treatment [6]. Another study found absenteeism from work to be the main cost driver in rehabilitation after lumbar disc surgery [7]. As patients with limited recovery highly contribute to these indirect costs, an important aim of postoperative treatment is to prevent the development of chronic symptoms [8]. In an RCT, we therefore compared an exercise therapy intervention starting in the first postoperative week with no referral for early rehabilitation [9]. The current paper reports the results of the economic evaluation that we conducted alongside this RCT. The aim was to assess the cost-effectiveness of referral for early rehabilitation after lumbar discectomy in comparison with no referral, from a societal perspective.

Methods

Participants and setting

The economic evaluation was performed alongside an RCT conducted in the Netherlands from May 2012 to June 2015. The study protocol was approved by the Medical Ethics Review Board of the VU University Medical Centre and subsequently by the local review board of each participating hospital. The trial was registered in the Netherlands Trial Register (NTR3156). A detailed description of the trial design has been published previously [9].

Neurosurgeons of the participating hospitals informed all patients with a clear indication for lumbar disc surgery about the study and referred potentially eligible participants to the research team prior to surgery. Inclusion criteria were: lumbar disc herniation confirmed by MRI and physical signs of nerve root compression corresponding to the level of disc herniation, between 18 and 70 years of age, able to fill out Dutch questionnaires, and the provision of written informed consent. Exclusion criteria were: cauda equina syndrome, neurogenic claudication, co-morbidities of the lumbar spine (e.g., fractures, carcinomas, osteoporosis), prior spinal surgery in the last 12 months, previous lumbar disc surgery at the same level and same side, pregnancy, or contra-indications for exercise therapy (e.g., acute respiratory or cardiovascular complaints, acute systemic infections). After obtaining informed consent and baseline measurements and prior to hospital admission for surgery, a research nurse opened a sealed opaque envelope which contained the treatment allocation. To conceal treatment allocation, randomisation lists per hospital were generated by computer prior to study commencement by an independent researcher.

Intervention and control condition

All participants, regardless of treatment allocation, received usual hospital care. This treatment, provided by a physiotherapist or nurse, mainly consisted of providing advice and instructions for transfers and performing activities of daily living, in preparation for discharge.

Early rehabilitation

Participants in the intervention group received a referral for post-surgery exercise therapy in primary care starting the first week after discharge. During a six to eight week period, participants received one or two exercise therapy sessions per week, conform a treatment protocol designed for this trial including information and advice about rehabilitation. The main goal was to gradually extend activities of daily living from personal care to housekeeping tasks in the short term and return to work and sports and leisure activities in the long term. Treatment could be terminated before the end of the six to eight week period if the patient was fully recovered.

Control group

Participants assigned to the control group did not receive a referral for rehabilitation immediately after discharge from hospital. Patients could consult their neurosurgeon or general practitioner in case of recurring or increasing complaints, but no exercise therapy or other allied health care intervention was initiated in the first six to eight weeks.

Outcome measures

Outcome measures were assessed pre-operatively (baseline) and 3, 6, 9, 12 and 26 weeks post-operatively and included functional status, pain intensity, global perceived effect, general health and health-related quality of life. Functional status was assessed by the Oswestry Disability Index (ODI version 2.1.a) [10]. The ODI consists of 10 questions assessing aspects of daily living, each being scored on a six-point scale, ranging from 0–5. The total score comprises the 10 item-scores and ranges from 0 (no difficulty) to 50 (maximal difficulty). The ODI score was dichotomised into recovered and not recovered using a cut off of 30% decrease in ODI at any follow-up moment as compared to baseline. Pain intensity was measured for leg pain and low back pain on an 11-point numerical rating scale (0=no pain to 10=worst imaginable pain) [11]. Average pain intensity over the preceding week was measured, for leg pain and low back pain separately. Global perceived effect was evaluated with the seven-point Global Perceived Effect scale (GPE), ranging from "completely recovered" to "worse than ever". This scale was dichotomised into success (completely and much recovered) and non-success (slightly recovered, no change, slightly worse, much worse and worse than ever).

The Medical Outcome Study Short Form 12 (SF-12) was used to assess general health status [12]. The 12 items cover the components physical function and mental health. Component scores can be calculated with scores ranging from 0–100 per component. Higher scores reflect better health. The EuroQol (EQ-D5-3L) was administered to assess health-related quality of life [13]. This instrument evaluates 5 dimensions of quality of life on a three-point scale (no problems, moderate problems and severe problems). Utilities based on the EQ-5D-3L were estimated using the Dutch tariff [14]. Quality-adjusted life years (QALYs) were calculated using linear interpolation between measurement points.

Cost measures

Cost data were collected at 6, 12 and 26 weeks post-surgery using cost questionnaires. Six-week recall periods were used for the cost questionnaires administered at 6 and 12 weeks post-surgery and a 14-week recall period for the cost questionnaire administered at 26 weeks post-surgery. Costs were measured from a societal perspective and included intervention, healthcare, informal care, absenteeism, and unpaid productivity costs. For all cost categories, only costs related to leg and back pain were considered.

Intervention costs were estimated based on the total number of physiotherapy and/or exercise therapy sessions the patient received during the intervention period. These sessions were valued using Dutch standard costs [15]. Healthcare costs included costs due to primary and secondary healthcare use and both prescribed and over-the-counter medication. Dutch standard costs were used to value primary and secondary healthcare utilization [15]. If unavailable, prices according to professional organisations were used. Medication use was valued using unit prices of the Royal Dutch Society of Pharmacy [16]. Informal care (i.e. care by family, friends, and all other kinds of volunteers) was valued using a Dutch shadow price of €13.74/hour [15]. A modified version of the Productivity and Disease Questionnaire (PRODISQ) was used to measure absence from paid work [17]. Absenteeism costs were valued in accordance with the friction cost approach (FCA) [18], using the estimated price of productivity losses per sickness absence day in the Netherlands based on 5-year age categories and gender [15]. The FCA assumes that costs are limited to the period needed to replace a sick worker (i.e., the friction period, which is estimated to be 23 weeks in the Netherlands) [18]. Unpaid productivity losses (i.e. all hours of volunteer work, and domestic and educational activities that patients were not able to perform due to their leg and back pain) were valued using a Dutch shadow price of €13.74/hour. Table 1 presents an overview of the cost prices used for valuing resource use. All costs were converted to 2014 Euros using consumer price indices. Because of the 26-week time horizon, costs were not discounted.

Table 1 Prices used in the economic evaluation

Cost category	Price (€, 2014)
Direct health care costs	
Primary care costs	
General practitioner, per visit	30.77
Physical therapy, per treatment session	39.57
Exercise therapy, per treatment session	38.47
Occupational health practitioner per visit	24.74
Secondary care costs	
Outpatient clinic, per visit	70.34
X-ray, per image	49.66
MRI scan, per scan	212.60
Hospitalisation, per day	502.27
Revision surgery, per procedure	2775.05
Direct non-healthcare costs	
Informal care, per hour	13.47
Indirect non-healthcare costs	
Absenteeism paid work, per hour	8.76-40.50
Absenteeism unpaid work, per hour	13.47

Data analysis

Analyses were performed according to the intention-to-treat principle. Descriptive statistics were used to compare baseline characteristics between intervention and control group participants and those with complete and incomplete data. Missing data were imputed using Fully Conditional Specification and Predictive Mean Matching [19] stratified by treatment group [20]. An imputation model was constructed, including variables related to the "missingness" of data, variables that differed between patients with complete and incomplete data, variables that predicted the outcomes, and all available midpoint and follow-up cost and effect measure values [19].Ten different data sets were created to reach a loss of efficiency lower than 5%. Data sets were analysed separately as specified below, after which pooled estimates were calculated using Rubin's rules [19].

To compare total and disaggregated costs between treatment groups, linear regression analyses were performed (crude and adjusted for confounders). Seemingly unrelated regression (SUR) analyses were performed to estimate total cost and effect differences while adjusting for confounders and taking into account the possible correlation between costs and effects. Incremental cost-effectiveness ratios (ICERs) were calculated by dividing the adjusted differences in total costs by the adjusted differences in effects. Bias-corrected and accelerated bootstrapping with 5000 replications was used to estimate the uncertainty surrounding the cost differences and ICERs. Bootstrapped incremental cost-effect pairs (CE-pairs) were plotted on cost-effectiveness planes to graphically illustrate the uncertainty around the ICERs [21]. A summary measure of the joint uncertainty of costs and effects was presented using cost-effectiveness acceptability curves (CEACs), which indicate the probability that the intervention is cost-effective in comparison with the control condition at different ceiling ratios (i.e. the maximum amount of money society is willing to pay to gain one extra unit of effect) [22].

Three sensitivity analyses were performed to assess the robustness of the results. In a first sensitivity analysis (SA1), only data of patients with complete cost and effect values were used (i.e. complete-case analysis). In a second sensitivity analysis (SA2), the SF-12 was used for estimating QALYs using the tariff of Brazier et al. [23]. In a third sensitivity analysis (SA3), a per-protocol analysis was performed, excluding control group participants receiving one or more treatment sessions and intervention group participants not receiving any sessions in the first eight weeks.

Results

A total of 356 patients were referred to the research team. Of those, 172 were either excluded, refused participation or could not be contacted.

Of the remaining 184 participants, 10 recovered before surgery could be performed and one participant did not undergo surgery because immediate angioplasty was required for an acute vascular complication unrelated to the disc herniation. Of 173 participants that underwent surgery, 4 participants were excluded due to cauda equina syndrome (n=2), carcinoma (n=1) and undergoing decompression for stenosis (n=1).

Complete data were available from 88% of the participants in the intervention group and 87% in the control group on the effect measures and from 80% and 74% on the cost measures, respectively. After 26 weeks there were no statistically significant differences between groups on any clinical outcome between the groups (table 2). Total costs in the intervention group were lower than in the control group, but this difference was not statistically significant (€-527; 95%CI -2846 to 1506). Costs that were higher in the intervention group included intervention costs (€257; 95%CI 226 to 295) and primary care costs (€364; 95%CI 71 to 630). The control group had higher costs for informal care -€602; 95%CI -1582 to -172) and unpaid productivity (€-449; 95%CI -1005 to -132). Absenteeism costs were the largest contributor to total costs in both groups, but did not differ significantly between the groups (table 2).

6

Table 2 Mean cost per participant in the intervention and control group and mean cost differences between groups during the 26 weeks follow-up

Cost category	Intervention n=92, mean (SEM)	Control n=77, mean (SEM)	Cost difference crude, mean (95%CI)	Cost difference adjusted, mean (95%CI)
Intervention costs	257 (16)	0 (0)	257 (228 to 290)	257 (226 to 295)
Medical costs	1240 (117)	997 (192)	243 (-217 to 639)	241 (-205 to 688)
Primary care	1046 (96)	652 (131)	394 (77 to 677)	364 (71 to 630)
Secondary care	172 (67)	308 (117)	-136 (-454 to 92)	-108 (-402 to 143)
Medication	22 (8)	37 (13)	-15 (-48 to 10)	-15 (-48 to 9)
Informal care costs	375 (74)	987 (334)	-611 (-1817 to -165)	-602 (-1582 to -172)
Absenteeism costs	4404 (559)	4113 (718)	291 (-1629 to 1967)	27 (-1707 to 1591)
Unpaid productivity costs	209 (67)	693 (211)	-484 (-1108 to -157)	-449 (-1005 to -132)
Total	6486 (626)	6790 (957)	-304 (-2812 to 1765)	-527 (-2846 to 1506)

The results of the cost-effectiveness analyses are presented in table 3. For all outcomes, the CE-pairs were scattered around the four quadrants of the CE-

Table 3: Differences in pooled mean costs and effects (95% Confidence intervals), incremental cost-effectiveness ratios, and the distribution of incremental cost-effect pairs around the quadrants of the cost-effectiveness planes

Analysis	Sample size		Outcome	ΔC (95% CI)	ΔE (95% CI)	ICER	Distribution CE-plane (%)			
	Intervention	Control		€	Points	€/point	NE[1]	SE[2]	SW[3]	NW[4]
Main analysis - Imputed dataset	92	77	ODI (Range: 0 - 1)	-518 (-2834 to 1500)	0.01 (-0.10 to 0.11)	-85571	10.5	37.0	32.0	20.5
	92	77	Leg pain (Range: 0 – 10)	-571 (-2923 to 1410)	0.12 (-0.70 to 0.95)	-4590	8.2	32.2	37.1	22.6
	92	77	Back pain (Range: 0 – 10)	-578 (-2889 to 1455)	0.43 (-0.36 to 1.22)	-1608	2.0	12.7	58.2	27.1
	92	77	Perceived recovery (Range: 0 - 1)	-513 (-2796 to 1466)	0.01 (-0.13 to 0.15)	-50958	13.1	45.2	22.5	19.2
	92	77	QALYs (Range: 0 - 1)	-678 (-3048 to 1357)	0.01 (-0.02 to 0.04)	-85394	13.2	55.3	17.7	13.8
SA1 – Complete cases	74	57	ODI (Range: 0 - 1)	-478 (-3312 to 1732)	0.013 (-0.96 to 0.122)	-3761	15.7	44.1	19.8	20.3
	74	57	Leg pain (Range: 0 – 10)	-487 (-3459 to 1783)	0.24 (-0.58 to 1.07)	-1992	57.6	22.3	41.7	30.2
	74	57	Back pain (Range: 0 – 10)	-496 (-3413 to 1726)	0.53 (-0.25 to 1.32)	-928	2.1	9.1	55.2	33.6
	74	57	Perceived recovery (Range: 0 - 1)	-397 (-3227 to 1968)	0.01 (-0.13 to 0.16)	-29217	14.5	43.8	18.7	22.1
	74	57	QALYs (Range: 0 - 1)	-515 (-3396 to 1749)	-0.00 (-0.03 to 0.03)	1458267	9.8	23.9	39.9	26.3
SA2 – SF-6D	92	77	QALYs (Range: 0 - 1)	-637 (-3002 to 1381)	0.001 (-0.006 to 0.008)	-625531	22.7	40.0	32.5	4.8
SA3 – Per-protocol	86	70	ODI (Range: 0 - 1)	-201 (-2612 to 1832)	0.01 (-0.11 to 0.14)	-15659	20.1	36.8	19.6	22.9
	86	70	Leg pain (Range: 0 – 10)	-245 (-2547 to 1890)	-0.16 (-0.98 to 0.65)	1330	22.7	42.8	15.8	18.8
	86	70	Back pain (Range: 0 – 10)	-231 (-2628 to 1824)	0.05 (-0.77 to 0.87)	-4500	14.2	27.6	30.2	27.9
	86	70	Perceived recovery (Range: 0 - 1)	-129 (-2547 to 1866)	0.01 (-0.14 to 0.16)	-12240	20.6	35.8	17.9	25.7
	86	70	QALYs (Range: 0 - 1)	-329 (-2760 to 1738)	0.01 (-0.02 to 0.04)	-34438	22.7	50.0	10.7	16.6

[1] Refers to the northeast quadrant of the CE-plane, indicating that early rehabilitation is more effective and more costly than no referral for early rehabilitation
[2] Refers to the southeast quadrant of the CE-plane, indicating that early rehabilitation is more effective and less costly than no referral for early rehabilitation
[3] Refers to the southwest quadrant of the CE-plane, indicating that early rehabilitation is less effective and less costly than no referral for early rehabilitation
[4] Refers to the northwest quadrant of the CE-plane, indicating that early rehabilitation is less effective and more costly than no referral for early rehabilitation

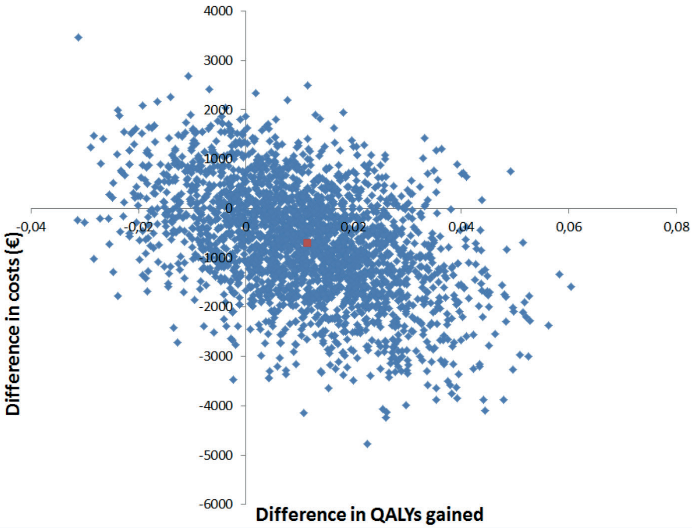

Figure 1 Cost-effectiveness planes indicating the distribution of incremental cost–effect pairs around its four quadrants

plane indicating a high level of uncertainty around the estimates (figure 1 CE plane QALY's). The CEACs showed that the maximum probabilities of cost-effectiveness for functional status, leg or back pain and recovery were 0.68, 0.70 and 0.70, respectively (data not shown). For QALYs, the CEAC indicated that if society is not willing to pay anything per QALY gained, the probability of cost-effectiveness is 0.73 (figure 2). This probability remained similar with a willingness-to-pay of 0.75 at a ceiling ratio of €32,000/QALY. The results of the sensitivity analyses did not substantially differ from the main analysis (table 3). For the per protocol analysis, the difference in costs was smaller than in the main analysis with a similar difference in QALYs. However, none of these differences were statistically significant.

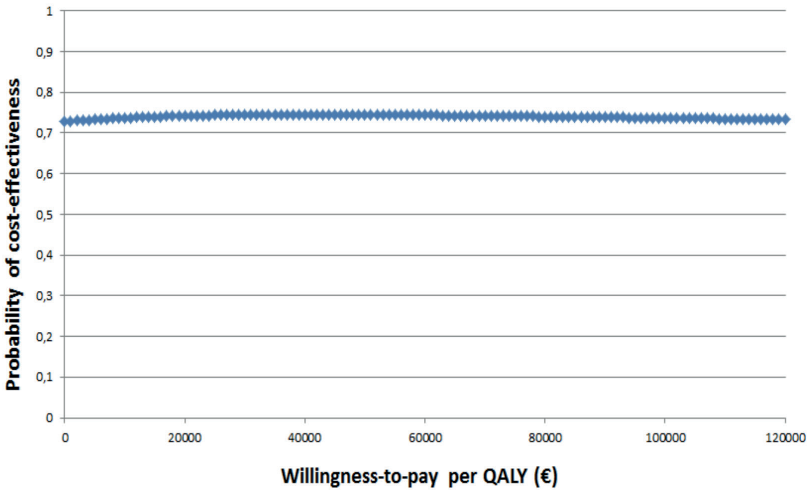

Figure 2 Cost-effectiveness acceptability curves indicating the probability of early rehabilitation being cost-effective in comparison with no referral for early rehabilitation for different values (€) of willingness-to-pay per QALY

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Discussion

This study investigated the cost-effectiveness of rehabilitation after lumbar disc surgery starting immediately after discharge from the hospital, from a societal perspective. The intervention had no significant effect on societal costs and on any clinical outcome measure in comparison with no referral for early rehabilitation. The probabilities of cost-effectiveness for functional status, recovery, and leg and back pain were relatively low at all ceiling ratios (i.e., maximum probability of 0.68 to 0.70) and the probability of cost-effectiveness for QALYs was 0.75 at a willingness-to-pay of €32,000/QALY. Based on these findings, the intervention cannot be considered cost-effective in comparison with control. The results of the sensitivity analyses were in line with the main analysis, indicating that the findings were relatively robust.

The total societal costs were not significantly different between the groups, and it is known that cost data are right skewed and therefore require large sample sizes to detect relevant differences. As in most RCTs, the sample size calculation of the current trial was based on the primary effect measures which might have underpowered it to detect a relevant difference in costs. However, as there were no differences in clinical effects between the intervention and control groups, differences in costs are not expected. Skewness of the data probably affected power, but the point estimates of the clinical effects are too small to consider these differences to be clinically relevant. Therefore, lack of power does not seem a problem in this study.

The only other cost-effectiveness study [6] that compared post-operative rehabilitation to no treatment found no significant differences in costs and effects, similarly to our study. The CEAC of that study showed that the probability of cost-effectiveness increased with an increased willingness-to-pay to approximately 0.52 at a ceiling ratio of £50,000/QALY [6], which is lower than in our study. The study included both patients with lumbar disc herniation and patients with stenosis, and reported inpatient nights as the largest contributor to total costs. Moreover, this study did not include work absenteeism, whereas this was the main cost driver in our study. The only other economic study of rehabilitation after lumbar disc surgery, comparing two types of post-operative rehabilitation, included the same cost categories as in our study, and also found absenteeism to be the largest contributor to total costs [7]. To reduce these high costs, it is of utmost importance to develop an intervention to speed up return to work (RTW) after surgery. A rehabilitation-oriented approach in insurance medicine effectively increased RTW rates compared to usual care insurance medicine [24]. In this intervention, starting 6 weeks post-surgery, a medical adviser coordinated a multidisciplinary approach including all relevant healthcare providers to achieve early return to work. Future research might, therefore, focus on investigating the cost-effectiveness of similar multidisciplinary interventions aiming at an early RTW.

The pragmatic RCT design was an important strength of the present study, as it allowed for the evaluation of the intervention's cost-effectiveness in a real world situation and to prospectively collect cost data. The pragmatic design enhanced the external validity (i.e., generalisability), while the randomisation guaranteed the internal validity. Other strengths were the use of state of the art statistical techniques (multiple imputation to handle missing data, SUR analyses to account for the possible correlation between costs and effects, and bootstrapping to estimate the uncertainty surrounding cost differences and ICERs). A limitation of this study is that we relied on self-reported cost data. Health insurance claim data and sickness absence data are practically inaccessible in the Netherlands, as it requires the cooperation of over 30 different insurance companies and employers of all employed participants. The self-report might have caused recall bias. However, given the recommended 3-month recall period for absenteeism [25], we do not expect that recall bias was an important issue. Besides, any recall bias (for absenteeism or health care costs) is likely to have affected both groups equally.

In conclusion, from the societal perspective, rehabilitation after lumbar disc surgery starting immediately after hospital discharge was not cost-effective compared to no referral for early rehabilitation.

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