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Cost-Effectiveness of Physical Therapy and General Practitioner Care for Sciatica

Pim A. J. Luijsterburg, PhD,* Leida M. Lamers, PhD,† Arianne P. Verhagen, PhD,* Raymond W. J. G. Ostelo, PhD,‡ Hans J. M. M. van den Hoogen, PhD, MD,§ Wilco C. Peul, MD,¶‖ Cees J. J. Avezaat, PhD, MD,** and Bart W. Koes, PhD*

Study Design. An economic evaluation alongside a randomized clinical trial in primary care. A total of 135 patients were randomly allocated to physical therapy added to general practitioners' care (n = 67) or to general practitioners' care alone (n = 68).

Objective. To evaluate the cost-effectiveness of physical therapy and general practitioner care for patients with an acute lumbosacral radicular syndrome (LRS, also called sciatica) compared with general practitioner care only.

Summary of Background Data. There is a lack of knowledge concerning the cost-effectiveness of physical therapy in patients with sciatica.

Methods. The clinical outcomes were global perceived effect and quality of life. The direct and indirect costs were measured by means of questionnaires. The follow-up period was 1 year. The Incremental Cost-effectiveness Ratio (ICER) between both study arms was constructed. Confidence intervals for the ICER were calculated using Fieller's method and using bootstrapping.

Results. There was a significant difference on perceived recovery at 1-year follow-up in favor of the physical therapy group. The additional physical therapy did not have an incremental effect on quality of life. At 1-year follow-up, the ICER for the total costs was €6224 (95% confidence interval, −10419, 27551) per improved patient gained. For direct costs only, the ICER was €837 (95% confidence interval, −731, 3186).

Conclusion. The treatment of patients with LRS with physical therapy and general practitioners'care is not more cost-effective than general practitioners'care alone.

Key words: lumbosacral radicular syndrome, sciatica, physical therapy, cost-effectiveness, general practitioner.
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The lumbosacral radicular syndrome (LRS), also called sciatica, is a disorder with radiating pain in the leg below the knee in 1 or more lumbar or sacral dermatomes, and can be accompanied by phenomena associated with nerve root tension or neurologic deficits.[1–4] A prolapsed disc is a frequent cause of LRS, but other causes include spinal or lateral recess stenosis, tumors, and radiculitis.[4,5] The incidence of LRS in the Netherlands is estimated at 5 per 1000 persons a year.[5] LRS is not life-threatening, but it causes pain in the leg and disability, often resulting in utilization of healthcare resources and absenteeism from work.[5] The total, direct and indirect, costs of LRS in the Netherlands are estimated at 1.18 billion euro a year.[5] Therefore, there is a need to determine the most cost-effective intervention for LRS.

Most patients seeking medical care in the Netherlands will first visit a general practitioner (GP). In 1996, the Dutch College of General Practitioners published their first clinical guideline for LRS[6] and updated it in 2005.[4] There is consensus that treatment of LRS in the first 6 to 8 weeks should be conservative. Many conservative treatments are available for treating LRS, but most patients are referred to physical therapy (PT).[7] The effectiveness of conservative treatments is not yet clear, however.[8] A randomized controlled trial was performed to evaluate the effectiveness of PT added to GP care compared with GP care alone in patients with acute LRS.[9] The clinical effects at 1-year follow-up have been reported elsewhere.[10] This study aimed to assess the cost-effectiveness of PT and GP care for patients with acute LRS, compared with GP care only.

Methods

More detailed information about the methods of the LRS trial is presented elsewhere.[9] The Erasmus Medical Center Ethics Committee approved the procedures and design of this trial.

Study Population. Participating GPs (n = 112) in Rotterdam and the surrounding area invited patients with acute LRS to participate in the trial from May 2003 to November 2004. Table 1 shows the eligibility criteria.

Randomization. A concealed randomization procedure was used, which was based on a computer-generated randomization list developed by an independent person. In order to pre-

From the *Department of General Practice, Erasmus Medical Center, Rotterdam, The Netherlands; †Institute for Medical Technology Assessment, and ‡Institute for Research in Extramural Medicine, VU University Medical Center, Amsterdam, The Netherlands and Amsterdam School of Allied Health Education, Amsterdam, The Netherlands; §General Practice, Asten, The Netherlands; ¶Neurosurgery, Leids University Medical Center, Leiden, The Netherlands; ‖Neurosurgery, Medical Center Haaglanden, the Hague, The Netherlands; and the **Department of Neurosurgery, Erasmus Medical Center Rotterdam, Rotterdam, The Netherlands.
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Address correspondence and reprint requests to Pim A. J. Luijsterburg, PhD, Erasmus MC, Department of General Practice, PO Box 2040, 3000 CA Rotterdam, The Netherlands; E-mail: p.luijsterburg@erasmusmc.nl

Table 1. Selection Criteria for Trial Eligibility

Inclusion
Radiating (pain) complaints in the leg below the knee
Severity of complaints scored above 3 on an 11-point NRS (0 = no complaints; 10 = maximum complaints)
Duration of the (pain) complaints less than 6 wk
Age between 18 and 65 yr
Able to speak and read Dutch
Presence of one of the following symptoms:
More pain on coughing, sneezing or straining
Decreased muscle strength in the leg
Sensory deficits in the leg
Decreased reflex activity in the leg
Positive straight leg raising test
Exclusion
Radiating (pain) complaints in the preceding 6 mo
Back surgery in the past 3 yr
Treated with epidural injections
Pregnancy
Comorbidity that determines overall well-being
Direct indication for surgery (unbearable pain, fast progression of paresis or cauda equina syndrome)
Expected loss to follow-up (*i.e.,* moving to another part of the country, long-lasting foreign holiday)

NRS indicates Numerical Rating Scale.

Table 2. Overview Unit Costs in the Economic Evaluation

	Cost (€)*
Direct healthcare costs	
Physical therapy (per visit)	22.75
General practitioner (per visit)	20.20
Manual therapy (per visit)	25.90
Cesar or Mensendieck therapy (per visit)	23.00
Consultation specialist in hospital (per visit)	56.00
Hospitalization (per day)	337.00
Surgery due to sciatica (laminectomy)	1149.94
Direct non-healthcare costs	
Help in housekeeping (per hour)	8.30
Indirect costs	
Absence from paid work (per hour)†	34.98

*Price according to Dutch guidelines[17] or according to professional association (2005).
†Because we were only interested in the extent of productivity costs, an overall mean income per hour regardless of age or gender was used.

vent unequal treatment group sizes, block randomization was used with blocks of 10 patients.[11] The research assistant performed the randomization after baseline measurement.

Blinding. For obvious reasons, the GPs, physical therapists, and patients were not blinded for treatment allocation. The statistical analysis and interpretation of the findings were audited and verified by an independent and uninvolved statistician.

GP Care. All patients were treated by the GP according to their clinical guidelines.[6] GPs gave information and advice about LRS and, if necessary, they prescribed (pain) medication.

Physical Therapy. The treatment consists of exercise therapy as well as giving information and advice about LRS. Passive methods such as massage and manipulation techniques, or applications such as ultrasound therapy or electrotherapy were not allowed. The treatment protocol was developed in a consensus meeting with participating physical therapists (n = 61). They acted as coaches and guided the patient in order to stimulate return to activity. Both GP and PT interventions were restricted to a maximum of 9 treatments or consultations in the first 6 weeks after randomization.

Measurements. The primary outcome measure was global perceived effect (GPE), measured on a 7-point scale ranging from 1 = completely recovered to 7 = vastly worsened.[12–14] These ratings were dichotomized as improved ("completely recovered" and "much improved") *versus* not improved ("slightly improved," "not changed," "slightly worsened," "much worsened," and "worse than ever"). GPE was rated as the percentage of patients that reported to be "improved." EQ-5D was used as a secondary outcome measure.[15] This is a generic preference-based measure of health, whereas the GPE can be seen as a more disease-specific measure. EQ-5D scores can be converted into utilities to calculate quality-adjusted life years (QALYs).[16] The outcome measures and costs were assessed at baseline and cumulative at 3, 6, 12, and 52 weeks after randomization using questionnaires. The economic evaluation was performed from a societal perspective, meaning that all relevant costs and effects are measured regardless of who pays the costs and who benefits from the effects. Table 2 shows an overview of the costs used in the economic evaluation.

The direct healthcare costs were: costs of PT, GP care, medication, addition visits to other healthcare providers, and hospitalization. Direct non-healthcare costs were: costs of devices, out-of-pocket expenses, and costs of help in housekeeping. Indirect costs outside the healthcare system were the costs of production losses caused by absence from work.

The costs for paid work were calculated by using the friction cost approach (friction period, 154 days) based on the overall mean income of the Dutch population.[17,18] This method is based on the idea that organizations need a certain time span, the friction period, to restore the initial production level after an employee becomes absent from work.

Statistical Analysis. The statistical analysis was performed according to the intention-to-treat principle, analyzing all patients in the treatment group to which they were randomly allocated. Missing (item) values were assigned the last available score.

Differences in resource utilization between the 2 arms were assessed. Costs were calculated by multiplication of each unit of resource use by its unit price. A comparison in resource use between the arms will provide insight in major cost drivers. Dealing with the nonnormality of the cost data, a nonparametric test (Mann-Whitney *U*/Wilcoxon) can be used.[19]

For the cost-effectiveness analysis, both the primary outcome measure GPE and EQ-5D were used to calculate the health effects. When EQ-5D is used, the health benefits are expressed in terms of QALYs gained, *i.e.*, the economic evaluation is a cost-utility analysis.[20] The Incremental Cost-Effectiveness Ratio (ICER) on total costs and direct costs only between both study arms was constructed. Confidence intervals for the ICER were calculated using Fieller's method[21] (parametric approach) and using bootstrapping (nonparametric approach) and graphically presented on the cost-effectiveness plane. Furthermore, a cost-effectiveness acceptability curve was constructed.[22] The acceptability curve shows the probability that a treatment is cost-effective at a specific ceiling ratio.[19] No sensitivity analysis was undertaken, as most

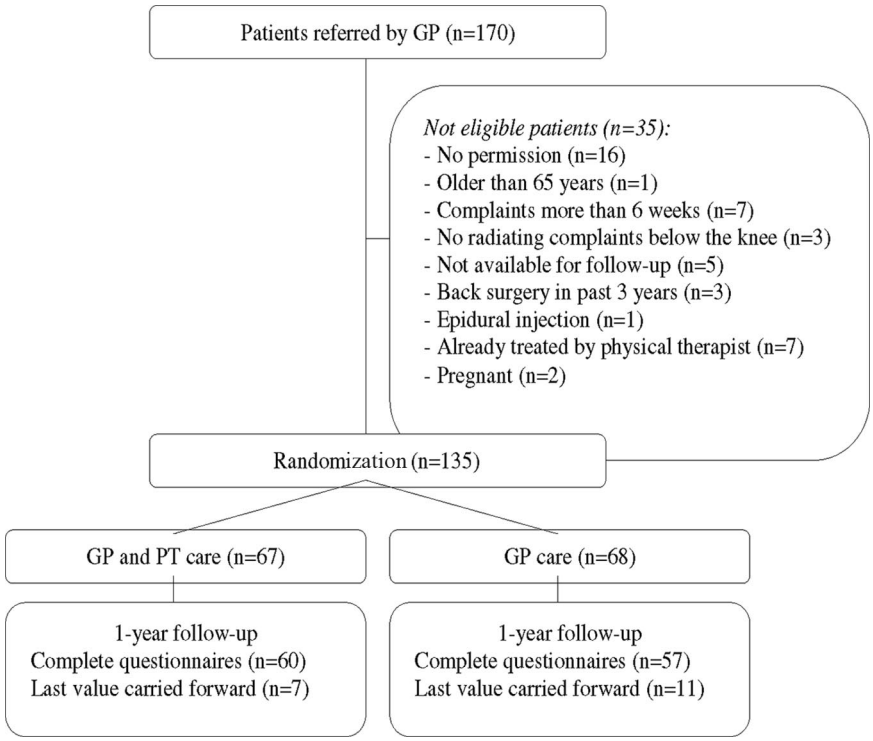

Figure 1. Flow chart of the trial.

variations in cost or health effect were included in the bootstrap estimates of the ICER.

■ Results

Included and randomized were 135 patients: 67 patients received GP care plus PT (the intervention group), and 68 patients received GP care only (the control group). Figure 1 shows the flow chart of the trial.

Four patients dropped out immediately after randomization because they no longer wished to participate: 1 in the intervention group and 3 in the control group. At 1-year follow-up, 117 patients (87%) completed their questionnaire, which included the cost data. Table 3 shows the baseline characteristics of the randomized patients.

Table 3. Baseline Characteristics of the 135 Patients Randomized in 2 Treatment Groups

Characteristic	GP + PT Care (n = 67)	GP Care Only (n = 68)
Female gender [n (%)]	38 (57)	27 (40)
Age (yr) [mean (SD)]	42 (10)	43 (12)
Paid job [n (%)]	48 (72)	50 (74)
Reporting sickness absence [n (%)]	34 (51)	32 (47)
Sickness absence from onset (days) [mean (SD)]*	3.1 (4.9)	4.2 (6.8)
Time between onset LRS and baseline in days [mean (SD)]	12.1 (10.1)	14.2 (10.2)
Never LRS in past [n (%)]	49 (73)	54 (79)
Taking medication for LRS [n (%)]	58 (87)	48 (71)
EQ-5D index score [mean (SD)]	0.39 (0.35)	0.41 (0.35)

*Before randomization.

The 2 groups were considered similar for all measured baseline characteristics. Therefore, only the unadjusted differences between the intervention and control group are presented.[10]

Health Effect of Additional Physical Therapy

After 1 year, there was a significant and a clinically relevant difference between the groups, on primary outcome (GPE) in favor of the intervention group.[10] Table 4 shows that 53 of 67 patients (79%) in the intervention group and 38 of 68 patients (56%) in the control group reported being "improved" (relative risk, 1.4; 95% confidence interval, 1.1; 1.8).

Table 5 shows that, at baseline and at 6 and 12 weeks follow-up, the mean of the utility was higher in the control group and at 6 weeks follow-up statistically significant different, in favor of the control group. At 1-year follow-up, the utility in the intervention group was higher.

Table 4. Data on Treatment Results at 3, 6, 12 and 52 Weeks After Baseline: Primary Outcome

Global Perceived Effect*	GP + PT Care Improved (n = 67) (%)	GP Care Only Improved (n = 68) (%)	RR (95% CI)
3 wk after baseline	30 (45)	22 (32)	1.4 (0.9; 2.1)
6 wk after baseline	38 (60)	30 (44)	1.3 (0.9; 1.8)
12 wk after baseline	47 (70)	42 (62)	1.1 (0.9; 1.5)
52 wk after baseline	53 (79)	38 (56)	1.4 (1.1; 1.8)

*Ratings on patient's globally perceived effect on a 7-point scale were dichotomized.
RR indicates relative risk; CI, confidence interval.

Table 5. Data on Utility at 3, 6, 12, and 52 Weeks Follow-up

	Baseline	6 Weeks	12 Weeks	52 Weeks
GP + PT care (n = 67)				
Utility [mean (SD)]	0.39 (0.35)	0.59 (0.34)*	0.65 (0.33)	0.76 (0.25)
GP care only (n = 68)				
Utility [mean (SD)]	0.41 (0.35)	0.70 (0.26)*	0.73 (0.30)	0.73 (0.27)

Utility was measured with Euroqol: EQ-5D index score; not measured at 3-week follow-up.
*Statistically significant difference in favor of GP care only group ($P = 0.049$).

Figure 2 shows the mean utility for the intervention and control group at baseline and at 6, 12, and 52 weeks of follow-up. Calculating QALYs for the groups showed no statistically significant difference in QALYs between the control (mean ± SD, 0.70 ± 0.25) and the intervention group (0.67 ± 0.26). This is illustrated in Figure 2, where the area between the curves is small.

Healthcare Utilization and Absence From Work

During the 1-year follow-up, 11 patients (16%) in the intervention group and 6 patients (9%) in the control group visited a neurologist. In the intervention group, 4 patients (6%) visited a neurosurgeon, 1 patient (2%) an orthopedic surgeon, and 4 patients (6%) received surgery due to LRS. In the control group, 5 patients (7%) visited a neurosurgeon, 2 patients (3%) an orthopedic surgeon, and 3 patients (4%) received surgery.

At 1-year follow-up, 30 patients (45%) in the intervention group reported a mean of 29.2 days (SD 48.4 days) absence from work and 25 patients (37%) in the control group reported a mean of 28.9 days (SD 72.3 days). These were not statistically significant differences.

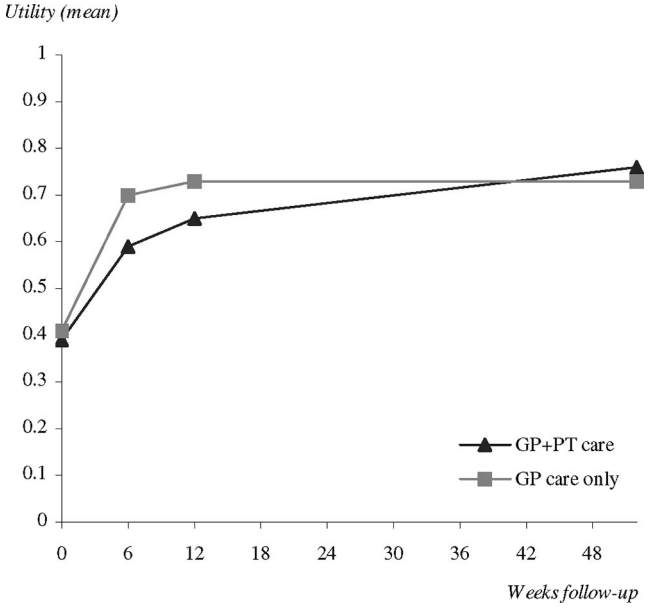

Figure 2. Mean utility at baseline and at 6, 12, and 52 weeks of follow-up.

Costs

Table 6 shows the direct and indirect costs from the intervention and control group at 1-year follow-up.

The total direct and indirect costs consisted mainly of production losses. At 3, 6, 12, and 52 weeks of follow-up, there were significant differences between groups on costs for PT visits, in favor of the control group. The total direct and indirect costs were also statistically significant different at the 4 follow-up moments, in favor of the control group.

Economic Evaluation

Because the additional PT resulted in a statistically significant higher proportion of patient recovered, GPE, the primary outcome measure, was used in the cost-effectiveness analysis. The cost-effectiveness analysis was conducted twice: 1 time taking only the direct costs into account and 1 time using total costs, *i.e.*, including direct and productivity costs.

In Table 7, point estimates for the ICERs are shown. The health effect was expressed in patient improved (GPE) gained. Confidence intervals for the ICER were calculated using Fieller's method.[21]

The ICER for the direct costs only was €837 per improved patient gained. This means that, for every extra patient in the intervention group that reported to be "improved," the extra direct costs were €837. The ICER for the total costs was €6224 per patient improved gained.

In the statistical analysis, besides the calculation of parametric confidence intervals, a bootstrap procedure was performed. In such a procedure, a random sample with replacement is taken from the original sample of patients, for both groups, with a size equal to the original sample size. For such bootstrap sample, again additional costs and effects and the ICER may be calculated. By repeating this procedure many times (here 2500), the uncertainty around the ICER can be assessed. For instance, each pair of additional costs and additional effects can be displayed in a scatter diagram (Figure 3). The ICER and 95% confidence interval estimated with the bootstrap procedure were similar to the results of the parametric approach presented in Table 6.

With the outcomes of the bootstrap procedure, a so-called cost-effectiveness acceptability curve was constructed (Figure 4). This curve shows, for every threshold value society may define for the ICER, the probability that the ICER is less than that value. When we assume a threshold of €600 direct costs per patient improved gained as acceptable, the ICER is acceptable with 35% certainty. When we assume a threshold of €1200 per patient improved gained as acceptable, the ICER is acceptable with 69% certainty. In case total costs are used, we have to assume a threshold of €4000 and €12,000, respectively, per patient improved gained as acceptable, to consider the ICER acceptable with 37% and 68% certainty (C/E-acceptability curve using total costs not shown).

Table 6. Cumulative Mean Direct and Indirect Costs (€) per Patient at 3, 6, 12, and 52 Weeks Follow-up

	3 Weeks [mean (SD)]	6 Weeks [mean (SD)]	12 Weeks [mean (SD)]	52 Weeks [mean (SD)]
GP + PT care (n = 67)				
Direct costs				
General practitioner	13.6 (18.1)	23.2 (30.5)	33.2 (28.3)	36.2 (37.3)
Physical therapy	87.3 (52.2)*	139.6 (77.6)*	191.8 (125.2)*	241.4 (328.4)*
Manual therapy	2.7 (15.7)	3.5 (20.1)	10.8 (57.4)	35.2 (128.8)
Cesar or Mensendieck therapy	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	14.1 (83.8)
Neurologist in hospital	4.2 (14.8)	6.7 (26.7)	9.2 (26.9)	26.7 (77.0)
Neurosurgeon in hospital	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	7.5 (32.2)
Orthopedic surgeon in hospital	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	1.7 (13.7)
Hospitalization	5.0 (41.2)	5.0 (41.2)	5.0 (41.2)	135.8 (531.4)
Surgery due to sciatica	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	68.7 (274.5)
Medication for sciatica	13.3 (13.2)	31.0 (30.1)	50.7 (50.9)	74.9 (73.7)
Non-healthcare	4.1 (17.1)	5.3 (20.8)	8.5 (39.3)	12.3 (51.7)
Total direct costs	127.5 (90.7)*	210.7 (132.2)*	293.3 (165.9)*	619.3 (899.3)*
Indirect costs				
Production losses	1281.4 (1590.9)	2127.1 (2577.2)	3245.9 (4252.5)	5629.6 (9048.9)
Total direct and indirect costs	1408.9 (1616.8)*	2337.8 (2616.9)*	3539.2 (4320.8)*	6248.9 (9602.5)*
GP care only (n = 68)				
Direct costs				
General practitioner	25.0 (22.6)	33.9 (36.3)	38.9 (43.2)	44.6 (54.1)
Physical therapy	9.4 (28.4)*	18.1 (45.4)*	30.8 (80.1)*	76.9 (187.6)*
Manual therapy	1.9 (11.2)	1.5 (8.8)	12.2 (85.5)	10.7 (47.0)
Cesar or Mensendieck therapy	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	12.5 (65.8)
Neurologist in hospital	2.5 (11.6)	5.8 (19.7)	5.8 (21.9)	13.2 (44.5)
Neurosurgeon in hospital	0.0 (0.0)	0.8 (6.8)	3.3 (21.4)	3.3 (13.3)
Orthopedic surgeon in hospital	0.0 (0.0)	0.0 (0.0)	1.6 (9.5)	2.5 (15.1)
Hospitalization	0.0 (0.0)	54.5 (410.1)	74.3 (454.2)	148.7 (718.7)
Surgery due to sciatica	0.0 (0.0)	0.0 (0.0)	16.9 (139.5)	50.7 (237.9))
Medication for sciatica	11.4 (16.2)	24.9 (34.0)	40.9 (54.1)	62.0 (81.2)
Non-healthcare	5.3 (16.8)	5.5 (19.4)	7.2 (29.9)	10.7 (55.6)
Total direct costs	53.4 (45.4)*	143.5 (435.4)*	219.7 (616.8)*	425.1 (1043.3)*
Indirect costs				
Production losses	1196.4 (1756.4)	1728.4 (2696.8)	2613.2 (4826.1)	4379.8 (9060.1)
Total direct and indirect costs	1249.8 (1772.8)*	1871.9 (2846.5)*	2832.9 (5179.8)*	4804.9 (9803.2)*

*Statistically significant difference in favor of GP care only group (Mann-Whitney *U* test; $P < 0.0$).

We refrained from cost utility analysis because there was no effect on quality of life between the 2 groups together with higher costs for the intervention group. In case of no health effects, the intervention with the lowest costs is the preferred intervention.

■ Discussion

An economic evaluation was performed alongside a randomized clinical trial identifying the most cost-effective intervention for patients with LRS in primary care. PT added to GPs' care resulted in more perceived recovery than the GPs' care alone. However, the direct and indirect costs for the intervention group were higher than in the control group. If decision makers value additional perceived recovery at much less than €6244, GP care alone is probably the preferred strategy. If their valuation lies between €6244 and €12000, PT added to GP care is likely to be the best treatment for patients with LRS. Overall, given an ICER of €6244 per improved patient gained, this study suggests that PT provided no cost-effective addition to care in general practice for patients with LRS

Table 7. ICER and 95% Confidence Interval (Parametric Approach)

	ICER	95% Confidence Interval (Fieller Method)
Additional costs (€) per patient improved gained (direct costs)	837	−732; 3186
Additional costs (€) per patient improved gained (total costs)	6224	−10419; 27551

The total costs were dominated by productivity losses; the direct costs by the costs of PT. This means that treating patients with PT, as expected, resulted in more utilization of PT. But it could also mean that PT as treatment affected absence from work and therefore productivity costs. Nevertheless, an active treatment approach by physical therapists resulted in more perceived recovery in patients with LRS than GP care alone.[10]

In terms of QALYs gained, the additional PT showed no health effect. To calculate QALYs, patients were asked to complete EQ-5D at baseline and at 6, 12, and 52 weeks of follow-up. EQ-5D is a generic preference-based measure of health. An advantage of a generic instrument is that it can be used within many disease areas, and it enables policy makers to compare (the costs) of

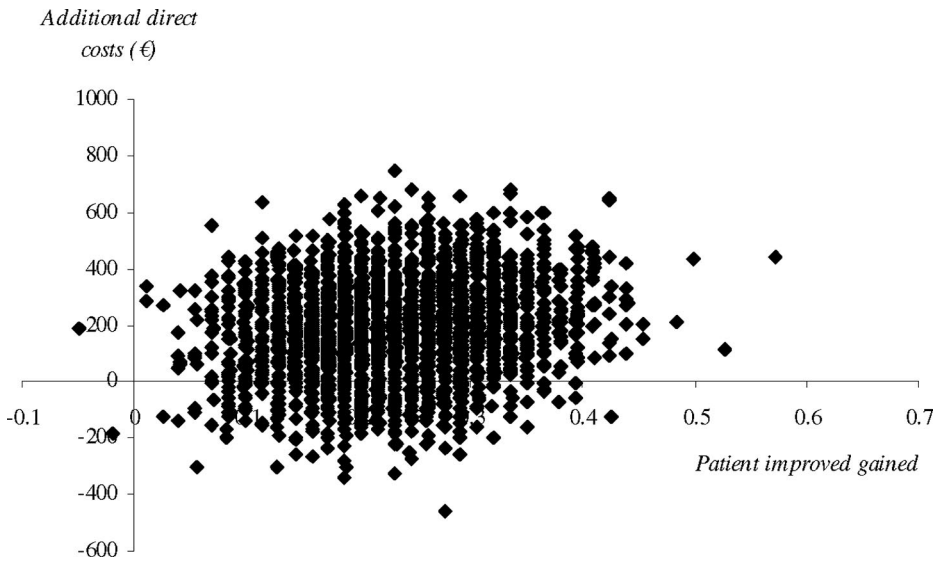

Figure 3. Scatter diagram of bootstrapped additional direct costs and effects.

health benefits across diseases. A disadvantage of generic instruments is that they do not capture disease-specific health improvements. The results of our study suggest that this is the case with EQ-5D. EQ-5D does not seem sensitive enough to capture the health effects of the additional PT.[23] Therefore, the cost-effectiveness of additional PT was assessed using GPE as the health outcome measure.

Waiting times are expected to influence costs, health effects, and cost-effectiveness of health care.[24] In our study, the waiting time for healthcare utilization was unknown. The economic evaluation performed ignored waiting time for healthcare utilization, and this might have biased the cost-effectiveness results. Moreover, it is very reasonable that this waiting time affected absence from work and therefore productivity costs. In future studies, there should be more attention paid to analyzing the impact of waiting time on absence from work and costs effects.

The measurements of the direct and indirect costs were cumulative at the follow-up moments. Therefore, recall bias in patients could have occurred because we asked for the direct and indirect costs from baseline to the follow-up moment. It is more precise and uniform to measure costs according to methods described in the handbook for cost studies from Oostenbrink *et al*.[17] Nevertheless, the patients were randomized in 2 groups; therefore, we suggest that the between-group conclusion about cost-effectiveness was not affected very much.

As far as known, no full economic evaluation alongside a randomized clinical trial that involved patients with LRS treated by physical therapy has yet been published. Our economic evaluation showed ICERs of €837 (direct costs) and €6224 (total costs) per improved patient gained.

It is therefore concluded that the treatment of patients with LRS with physical therapy and GP care is not more cost-effective than GP care alone.

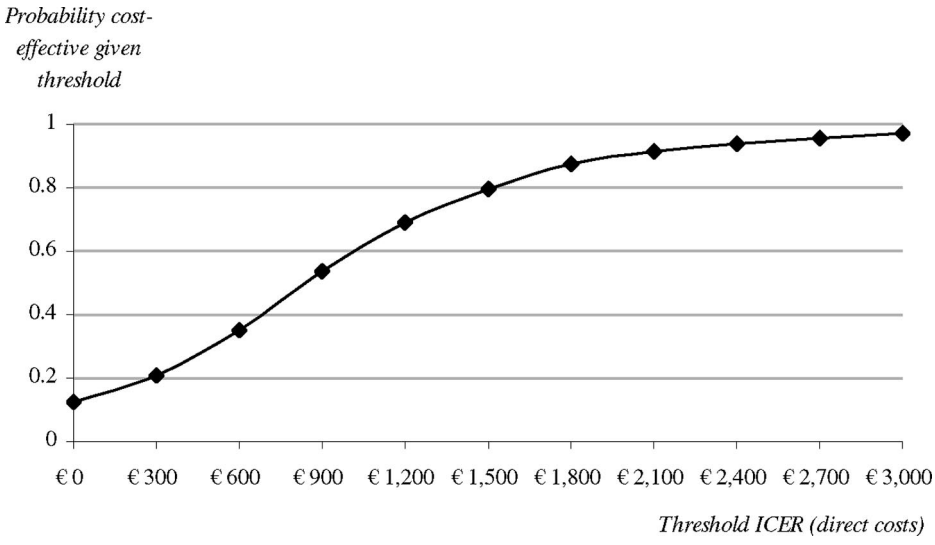

Figure 4. Acceptability curve presenting, for each possible threshold on the ICER, the probability that the ICER is acceptable.

■ Key Points

- At 1-year follow-up, there was a significant difference on perceived recovery in favor of the patients that received physical therapy.
- At 1-year follow-up, the additional physical therapy did not have an incremental effect on quality of life.
- At 1-year follow-up, physical therapy provided no cost-effective addition to care in general practice for patients with a lumbosacral radicular syndrome.

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